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Joint Preservation

Biosteon®

HA/PLLA Composite Anchors

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 hydrosis into materials that can be metabolized by the body[1]. 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.

Biosteon (HA/PLLA)

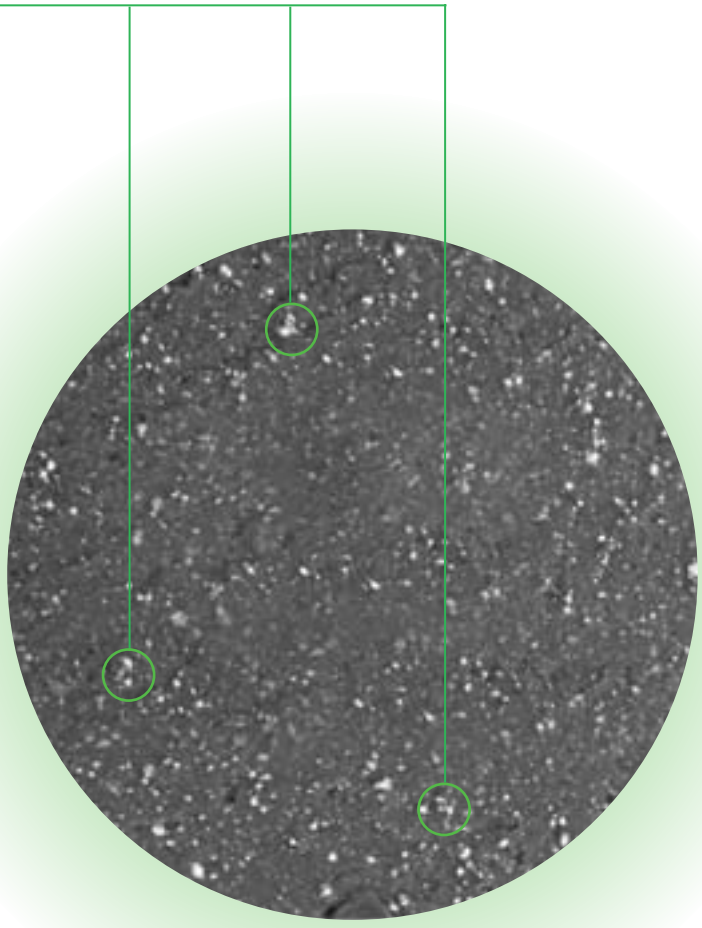
Biosteon is a composite of hydroxyapatite (HA) and non-crystalline poly-L-lactide (PLLA).

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 polymer[4], which helps prevent 'autocatalytic' degradation and premature loss of strength.

75% Amorphous PLLA

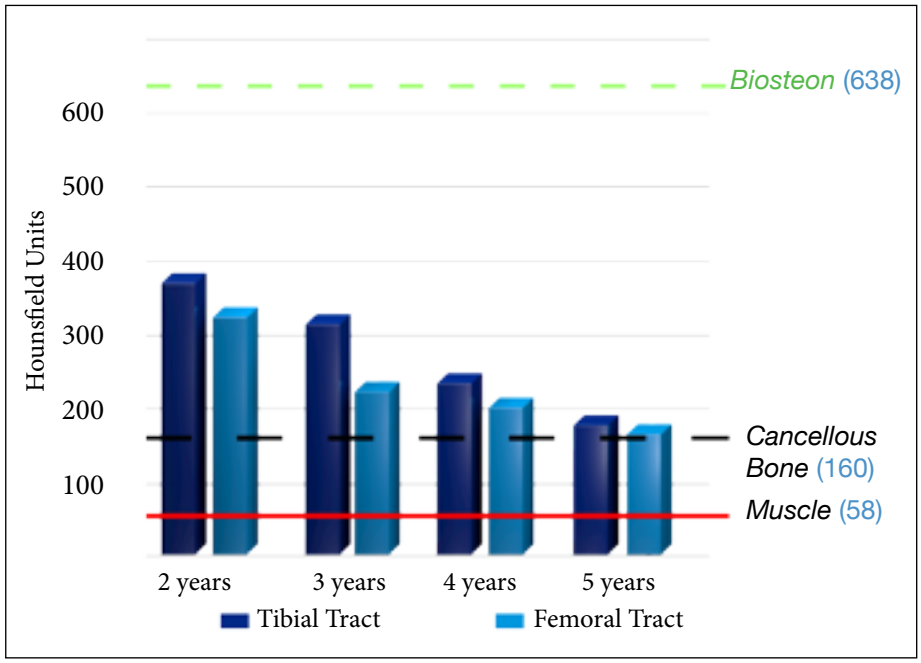
The amorphous PLLA in Biosteon provides structural integrity, biocompatibility and a controlled degradation rate[10].



Evidence

Clinical Evidence of Remodeling

Biosteon has been clinically shown to have excellent strength, proven biocompatibility, predictable resorption, osteoconductivity, and remodeling of the screw tract. The graph shows the density in the screw tract has become the same as cancellous bone over the course of the remodeling process[11].

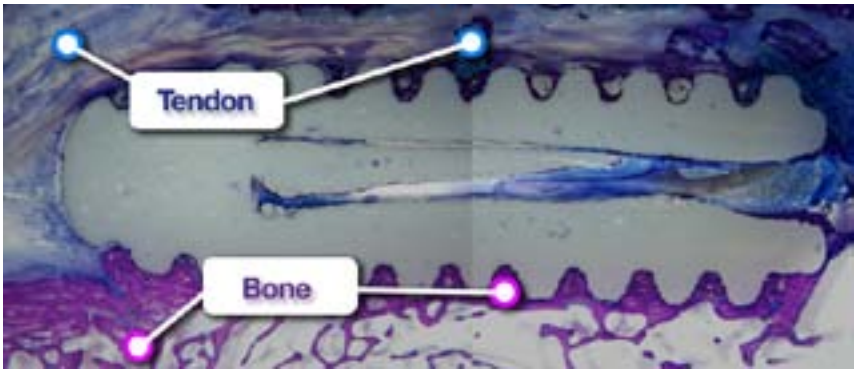


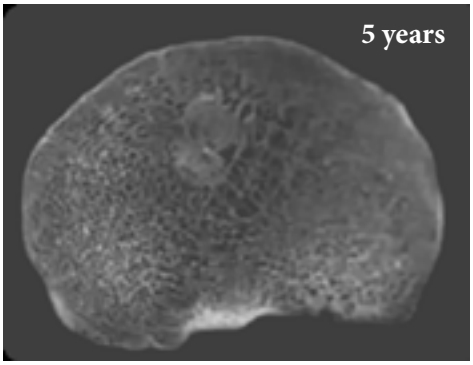
The CT images below show the density of the screw tract at 2 and 5 years[11]. The Biosteon screw is designed to maintain structural integrity and fixation strength during the healing process and remodel over time.

Biocompatibility

Biosteon HA/PLLA screws have been shown to support bone apposition rather than fibrous tissue formation[12].

The picture below shows an example of 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 screw[12].

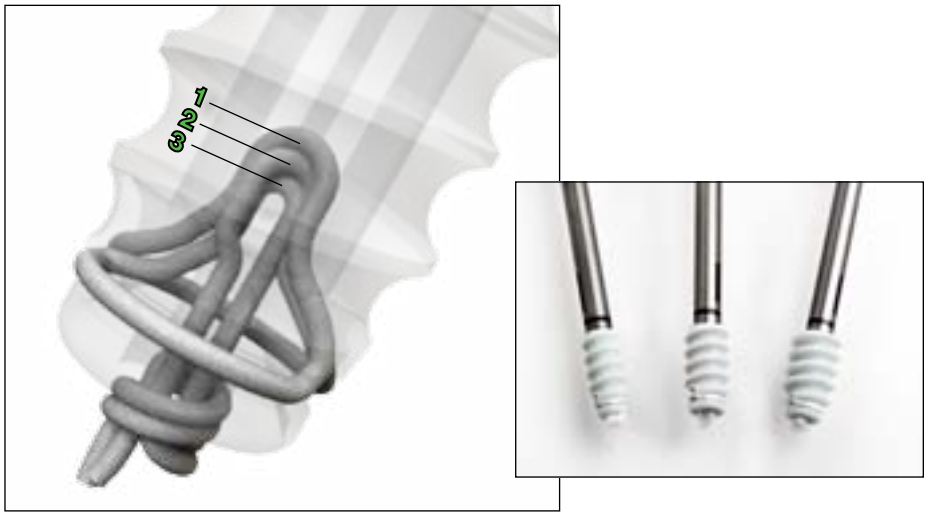




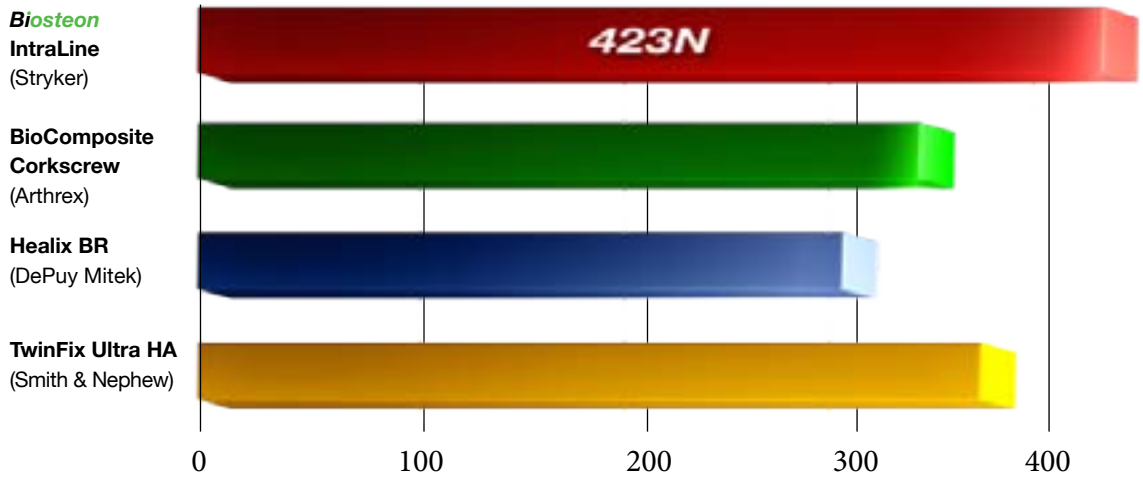
Competitive Advantages

Triple Loop

- Unique design
- Easy suture sliding
- Increased pull-out strength[13, 14]



Pull-out Strength[13, 14]



One pound force is approximately equal to 4.5 Newtons. All anchors above are 5.5mm.

Biosteon IntraLine®

	2 - Sutures		3 - Sutures	
	Without Needles	With Needles	Without Needles	With Needles
4.5mm	3910-200-080	x	x	x
5.5mm	3910-200-081	3910-200-082	3910-200-083	x
6.5mm	3910-200-084	3910-200-085	3910-200-086	x

Instrumentation

Ergonomic Handle

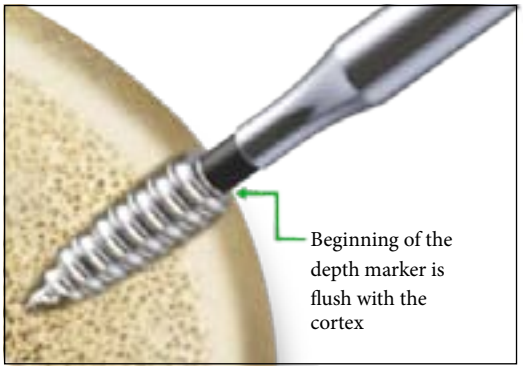
4.5mm Punch - Tap

5.5mm Punch - Tap

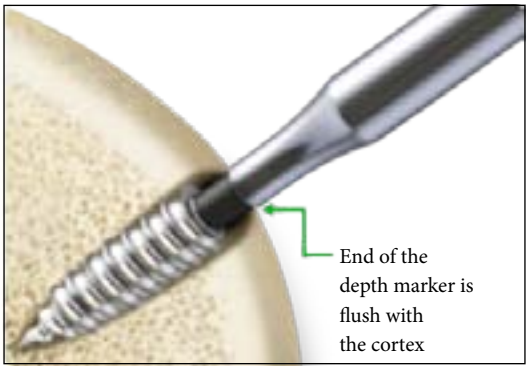
6.5mm Punch - Tap

Laser Band

The unique laser band allows surgeons to use one tap for both hard and soft bone.



Normal / Soft Bone



Hard Bone

Notes:

Notes:

Composite Anchors

PART NUMBER	DESCRIPTION
3910-200-080	4.5mm Biosteon IntraLine, 2 suture w/out needle
3910-200-081	5.5mm Biosteon IntraLine, 2 suture w/out needle
3910-200-082	5.5mm Biosteon IntraLine, 2 suture w/ needle
3910-200-083	5.5mm Biosteon IntraLine, 3 suture w/out needle
3910-200-084	6.5mm Biosteon IntraLine, 2 suture w/out needle
3910-200-085	6.5mm Biosteon IntraLine, 2 suture w/ needle
3910-200-086	6.5mm Biosteon IntraLine, 3 suture w/out needle
3910-002-045	4.5mm Biosteon IntraLine Punch - Tap
3910-002-055	5.5mm Biosteon IntraLine Punch - Tap
3910-002-065	6.5mm Biosteon IntraLine Punch - Tap

References
1. Hunt & Callaghan. "Polymer-hydroxyapatite composite versus polymer interference screws in anterior cruciate ligament reconstruction in a large animal model" Knee Surg Sports Traumatol Arthrosc 16:655, 2008.

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12. Hunt and Callaghan. Polymer-hydroxyapatite composite versus polymer interference screws in anterior cruciate ligament reconstruction in a large animal model. KSSTA 16(7); 655-660, (2008).

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14. Tech Report # DHFD11168

Literature Number: LJPBIB
MS/GS 05/12

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