Biosteon®
HA/PLLA Interference Screws

Biologically Inspired Fixation
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 body. However, bioabsorbable polymers are not osteoconductive, have no bone bonding ability and have little potential to be replaced by bone when resorbed. Polymers are also susceptible to autocatalytic degradation which can result in acidosis and sterile abscess formation at the site.

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, 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. The HA particles have a buffering effect on the acidic (lactic acid) degradation product of the polymer, 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.
**Design**

**Biosteon (HA/PLLA)**

**Wedge Shape**
The wedge shaped design of Biosteon allows for easier insertion and excellent fixation.11

**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 wall.12
Evidence

Biocompatibility

Biosteon HA/PLLA screws have been shown to support bone apposition rather than fibrous tissue formation\(^{13}\).

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 screw\(^{13}\).

Implant/Bone Integration

Use of Biosteon screws have been shown to improve the implant/bone integration by reducing tunnel widening\(^{14}\).
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 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.
A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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References
11. RD-10-015.
12. TR1277C-010.
14. Lind M, et al, Tibial bone tunnel widening is reduced by polylactate/hydroxyapatite interference screws compared to metal screws after ACL reconstruction with hamstring grafts. The Knee 6(6); 447-451, 2009.