

# BioComposite™ Interference Screws

A **STRONGER** Turn in ACL/PCL Reconstruction



Arthrex®

# BioComposite Interference Screw

The BioComposite Interference Screw is comprised of 30% biphasic calcium phosphate and 70% PLDLA and is intended for use as a fixation device for bone-patellar tendon-bone (BTB) and soft tissue grafts during ACL and PCL reconstruction procedures. The blending and binding process of the two materials adds significant strength to the implant by virtually eliminating stress risers while creating a macro and micro porous matrix to aid in the bone remodeling and replacement process. The cannulated hexalobe drive system enhances the screw family by providing one universal drive system for all screws and significantly improved torsional and insertion strength. Each screw fully seats on and is completely supported along the entire length of the driver tip.

Clinical reports suggest that biphasic calcium phosphate is safe and has excellent potential for orthopaedic applications. As the focus of many bone replacement studies, early bone formation can be connected to the favorable osteoconductive and bioresorbable properties within biphasic calcium phosphates.

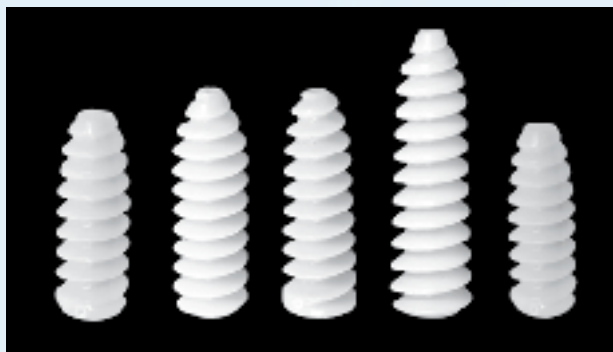
## Innovative Material Combination

### Biphasic Calcium Phosphate (BCP):

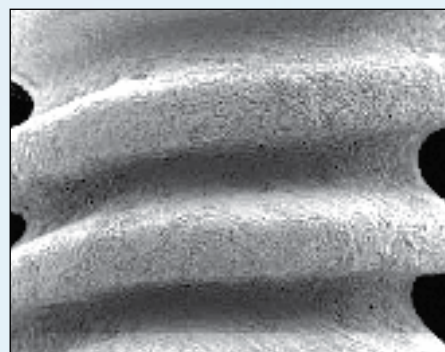
- Known osteoconductive material
- Provides superior balance of osteoblast adhesion and proliferation over hydroxyapatite (HA) or Beta-tricalcium phosphate ( $\beta$ -TCP) alone<sup>1</sup>
- Controlled solubility and release of calcium ions promotes more natural and balanced osteogenesis<sup>5,2</sup>
- Forms a strong dynamic interface with bone<sup>5,2</sup>
- Long track record as a safe biodegradable bone void filler, widely studied in multiple scientific articles<sup>4</sup>

### Amorphous PLDLA:

- Absorbs predictably over time<sup>3</sup>
- Greatly reduces chance of osteolytic lesions frequently seen with rapidly absorbing PGA polymers and copolymers
- No crystalline degradation product buildup at the implant site
- Long track record as a safe biodegradable polymer and widely studied in multiple scientific articles<sup>4</sup>
- Greatest potential for osteogenesis out of all of the polymers available<sup>4</sup>



23 mm, 28 mm Full Thread, 28 mm Round Delta Tapered, 35 mm Delta Tapered Screws and 20 mm BioComposite RetroScrew



SEM: 25x Magnification

## *Innovative Design*

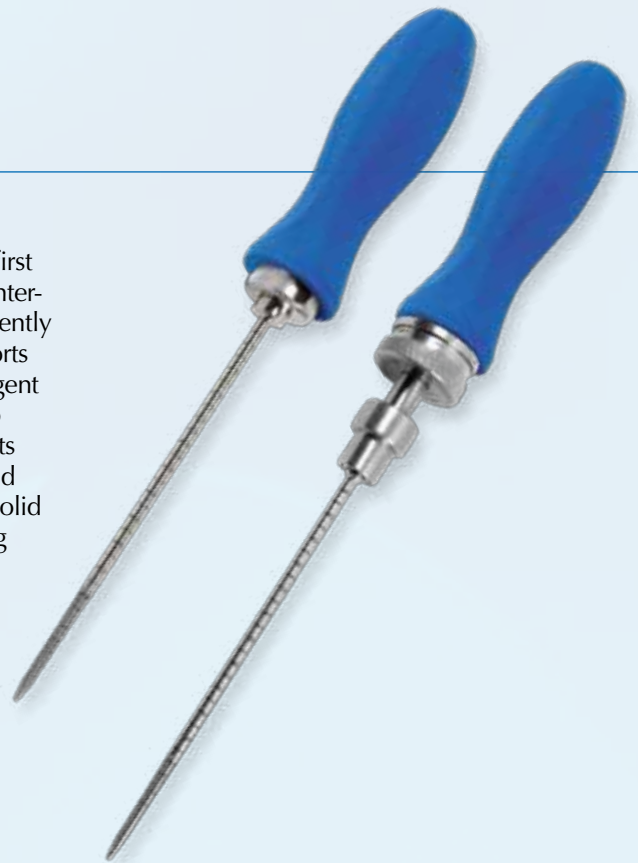
### **BioComposite Interference Screw:**

- The material blending and binding process is optimized to increase mechanical strength without becoming brittle, creating a homogenous blend of the components throughout the implant
- A macro and micro porous structure is formed promoting cell adhesion and proliferation
- Unmatched thread shear and blunting resistance<sup>1</sup>
- Optimized thread form to ease insertion and maximize soft tissue and bone fixation in cortical and cancellous bone
- A stepped taper design of the screw maximizes insertion torque as the screw is fully seated
- Material strength allows for implantation without tapping in most circumstances

## *BioComposite Screw Instrumentation*

### **Drivers**

The BioComposite Interference Screw Drivers are an industry-first for efficiency and strength. The hexalobe design of the driver tip interfaces completely with the BioComposite Interference Screw efficiently distributing torque, eliminating torque strip. The driver fully supports the entire length of the screw, eliminating screw breaking if divergent screw insertion is encountered. The driver tips are laser marked to signify when each screw is fully seated on the driver, and the shafts are laser marked in 5 mm increments to facilitate tunnel sizing and verification of screw insertion depth. The drivers are available in a solid handle version and a quick connect version to use with a ratcheting handle. These cannulated drivers allow for insertion into the joint over a flexible guide wire.



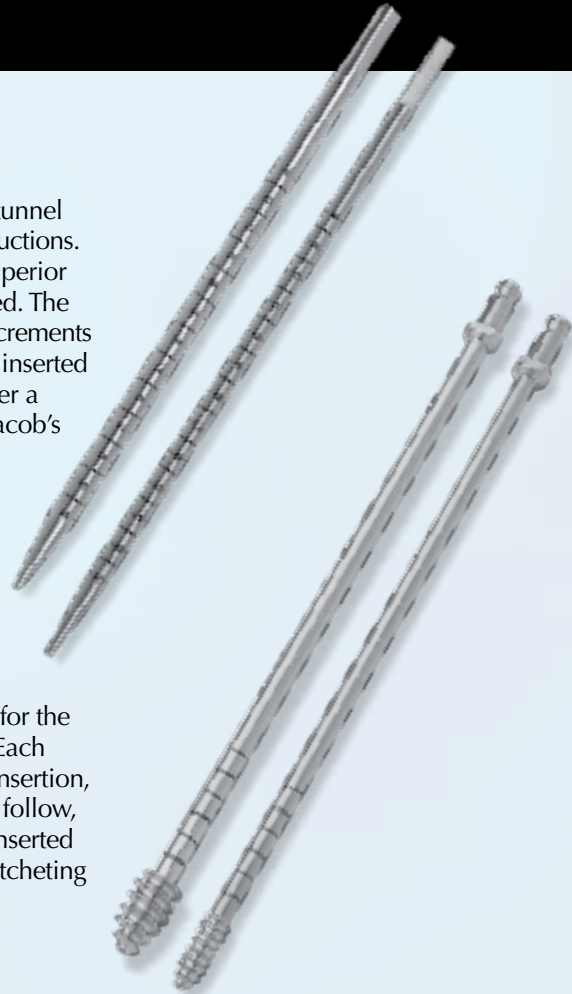
*Hexalobe Driver Interface of the BioComposite Screw*



*Cross-section of BioComposite Screw*

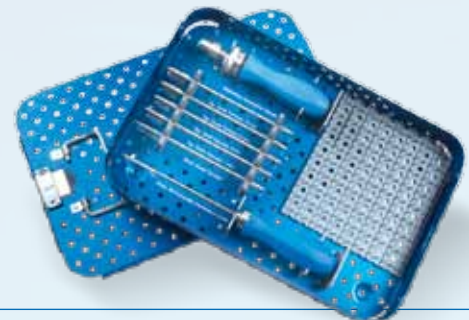
## Dilators

The BioComposite Interference Screw Dilators facilitate tunnel preparation prior to screw insertion during BTB ACL reconstructions. The gradual taper of the tip facilitates quick insertion and superior bone compaction, creating space for the screw to be inserted. The cannulated shafts of the dilators are laser marked in 5 mm increments to quickly verify proper insertion depth. The dilators can be inserted between the bone block of the graft and the tunnel wall over a flexible guide wire. The dilators mount on a gold-handled Jacob's Chuck Handle adaptor and are malleted into place.



## Taps

The BioComposite Interference Screw Taps are available for the 23 mm screws when extremely hard bone is encountered. Each has a blunt thread design that prevents graft damage upon insertion, yet creates an accurate threaded pathway for each screw to follow, reducing thread damage. These cannulated taps are easily inserted over a flexible guide wire and mount on a quick connect ratcheting or non-ratcheting handle.



## Instrumentation Case

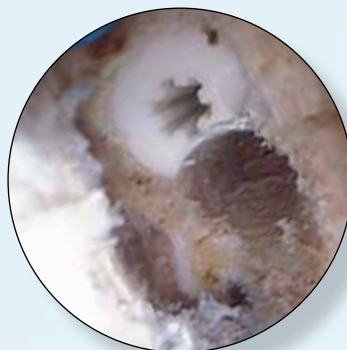
The BioComposite Screw Instrumentation Case conveniently holds both handled and quick connect screwdrivers, a ratcheting handle and quick connect taps. It features an extra space to hold additional instruments if needed and is lined with a silicone pad.

## New Revision Options

The unique bone-like characteristics of the BioComposite Screws facilitate over-drilling without compromising fixation.



*Original screw replaced with BioComposite Screw*



*New bone tunnel created*



*Revision ACLR carried out*

## Ordering Information

### ***BioComposite Interference Screws:***

BioComposite Interference Screw, 6 mm x 23 mm	AR-1360C
BioComposite Interference Screw, 7 mm x 23 mm	AR-1370C
BioComposite Interference Screw, 8 mm x 23 mm	AR-1380C
BioComposite Interference Screw, 9 mm x 23 mm	AR-1390C
BioComposite Interference Screw, 10 mm x 23 mm	AR-1400C
BioComposite Interference Screw, Full Thread, 7 mm x 28 mm	AR-1370TC
BioComposite Interference Screw, Full Thread, 8 mm x 28 mm	AR-1380TC
BioComposite Interference Screw, Full Thread, 9 mm x 28 mm	AR-1390TC
BioComposite Interference Screw, Full Thread, 10 mm x 28 mm	AR-1400TC
BioComposite Interference Screw, Full Thread, 11 mm x 28 mm	AR-1403TC
BioComposite Interference Screw, Full Thread, 12 mm x 28 mm	AR-1404TC
BioComposite Interference Screw, Round Delta Tapered, 8 mm x 28 mm	AR-5028C-08
BioComposite Interference Screw, Round Delta Tapered, 9 mm x 28 mm	AR-5028C-09
BioComposite Interference Screw, Round Delta Tapered, 10 mm x 28 mm	AR-5028C-10
BioComposite Interference Screw, Round Delta Tapered, 11 mm x 28 mm	AR-5028C-11
BioComposite Interference Screw, Delta Tapered, 9 mm x 35 mm	AR-5035TC-09
BioComposite Interference Screw, Delta Tapered, 10 mm x 35 mm	AR-5035TC-10
BioComposite Interference Screw, Delta Tapered, 11 mm x 35 mm	AR-5035TC-11
BioComposite Interference Screw, Delta Tapered, 12 mm x 35 mm	AR-5035TC-12
BioComposite RetroScrew, 7 mm x 20 mm	AR-1586RC-07
BioComposite RetroScrew, 8 mm x 20 mm	AR-1586RC-08
BioComposite RetroScrew, 9 mm x 20 mm	AR-1586RC-09
BioComposite RetroScrew, 10 mm x 20 mm	AR-1586RC-10

### ***BioComposite Interference Screw Instrumentation Set (AR-1996S) includes:***

BioComposite Interference Screw Driver	AR-1996CD
BioComposite Interference Screw Driver, quick connect	AR-1996CD-1
Ratcheting Screwdriver Handle	AR-1999
Tap, BioComposite Interference Screw, quick connect, 6 mm	AR-1998CT-06
Tap, BioComposite Interference Screw, quick connect, 7 mm	AR-1998CT-07
Tap, BioComposite Interference Screw, quick connect, 8 mm	AR-1998CT-08
Tap, BioComposite Interference Screw, quick connect, 9 mm	AR-1998CT-09
Tap, BioComposite Interference Screw, quick connect, 10 mm	AR-1998CT-10
Tap, BioComposite Interference Screw, quick connect, 11 mm	AR-1998CT-11
Tap, BioComposite Interference Screw, quick connect, 12 mm	AR-1998CT-12
BioComposite Interference Screw Instrumentation Case	AR-1996C

### ***Optional Instrumentation:***

Tunnel Notcher for Bio-Interference Screw	AR-1845
Non-Ratcheting Screwdriver Handle	AR-1999NR
Cannulated Dilator, 6 mm, for 23 mm BioComposite Screw	AR-1377C-06
Cannulated Dilator, 7 mm, for 23 mm BioComposite Screw	AR-1377C-07
Cannulated Dilator, 8 mm, for 23 mm BioComposite Screw	AR-1377C-08
RetroScrew Driver, thin	AR-1586R

### ***Disposable Accessories:***

Transtibial ACL Disposables Kit with Hall Style Blade, qty. 5	AR-1897S
Transtibial ACL Disposables Kit without Saw Blade, qty. 5	AR-1898S

### **References:**

1. Data on file
2. Blokhuis, et al, Properties of Calcium Phosphate Ceramics in Relation to their In Vivo Behavior, *Journal of Trauma: Injury, Infection and Critical Care*, Vol. 48, No. 1, 2000: 179-186.
3. Middleton and Tipton, Synthetic Biodegradable Polymers as Orthopedic Devices, *Biomaterials*, Vol 21, No 23, 2000: 2335-2346.
4. Weiler, et al, Biodegradable Implants in Sports Medicine: The Biologic Base, *Arthroscopy*, Vol 16, No 3, 2000: 305-321.
5. Daculsi, et al, Current State-of-the-Art of Biphasic Calcium Phosphate Bioceramics, *Journal of Materials Science*, Vol 14, No 3, 2003: 195-200.



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