BoneSync™ Calcium Phosphate Cement

Surgical Technique

Arthrex®

BoneSync™ Calcium Phosphate Cement

Features and Benefits

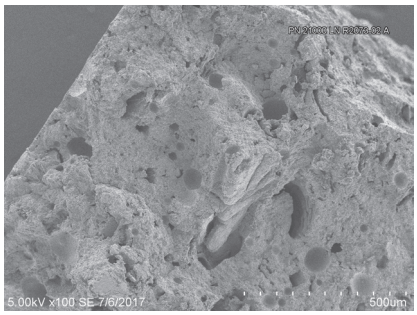
Instrument Features and Benefits

Features	Benefits
Self-contained mixing and delivery system	■ Improved convenience and safety ■ Decreased preparation time ■ Predictable material delivery
Injectable by hand or spindle drive	■ Reduced handling time ■ Increased precision and ease of application

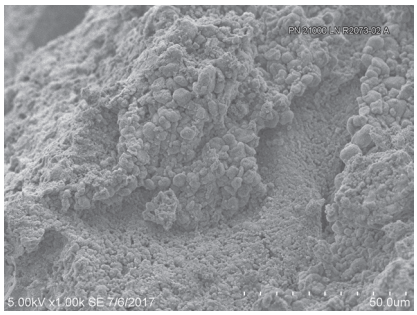
Product Features and Benefits

Features	Benefits
Fast-setting	■ Minimizes extension of procedure time
Isothermic reaction	■ Temperature of material during hardening does not cause cell necrosis
Hardware compatible	■ Drillable and provides supplemental compressive strength ■ Added flexibility for timing of hardware insertion
Blood and bone marrow aspirate (BMA) compatibility	■ Added flexibility for surgeon preference ■ Potential for improved bone remodeling
Collagen additive	■ Increased precision and ease of application as a putty ■ Versatile delivery method as an injectable putty ■ Minimal material loss during preparation and handling[1] ■ Captures autologous fluids for delivery to the surgical site ■ Improved integration with native bone ■ Maintains volume while setting

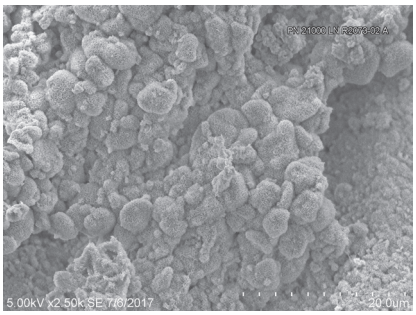
Surface of BoneSync cement after setting (collagen removed to demonstrate pore size of calcium phosphate cement).



100x magnification



1000x magnification



2500x magnification

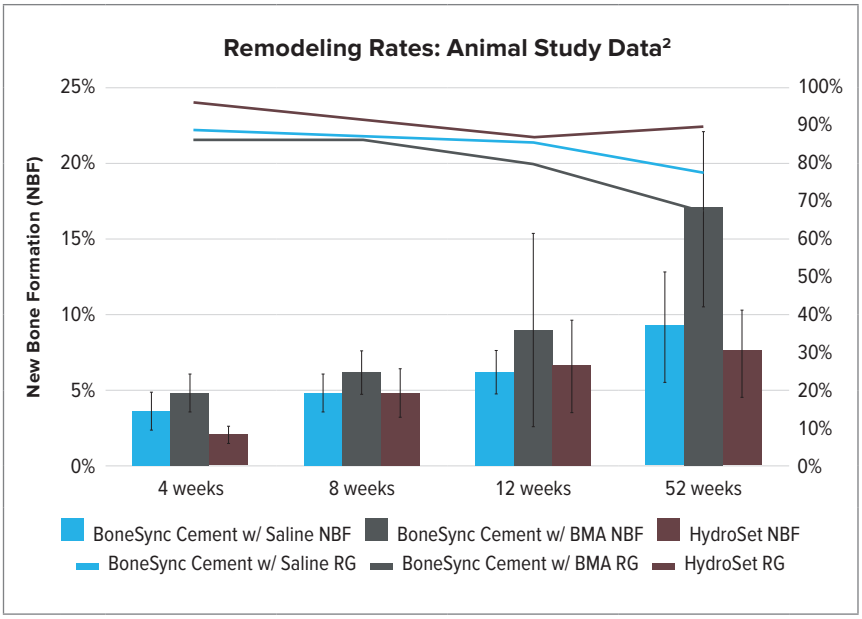
Injectable, Settable, Drillable Putty That Remodels Bone

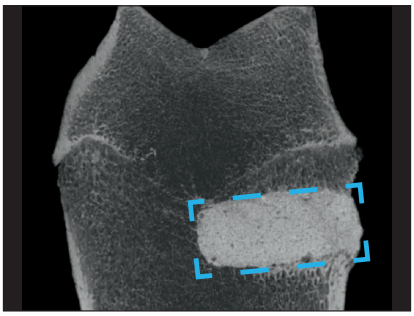
BoneSync™ cement offers improved handling in preparation and delivery, and can be mixed with saline, blood, and BMA, allowing for an affordable, easy-to-use, fast-remodeling, settable, and drillable biomimetic solution to fracture repair.

- Terminally sterilized
- Self-contained mixing and delivery syringe
- Injectable putty is cohesive and moldable

In Vivo Data

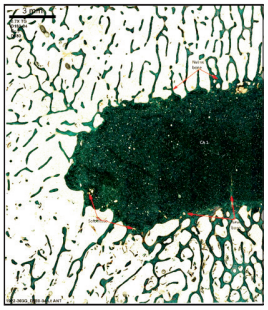
- Study investigated osseointegration and local histopathology response to BoneSync cement mixed with saline or BMA, Stryker HydroSet®, and one negative control (sham) in an ovine (sheep) bilateral femoral critically sized defect model.
- The test articles and control articles were implanted bilaterally into surgically created femoral condyle defects that measured 8 mm in diameter and 15 mm in depth.
- Evaluated bony ingrowth and remodeling at 4 weeks, 8 weeks, 12 weeks, and 1 year postimplantation.
- This data suggests there is a statistically significant amount of new bone growth at 52 weeks with BoneSync cement hydrated with BMA, as compared to with HydroSet. Note that HydroSet cannot be hydrated with autologous fluids.





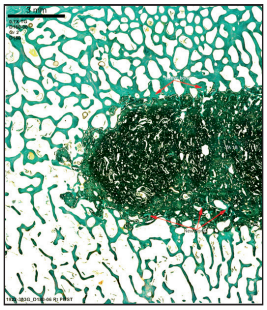
Critical-size defect with bone graft substitute

52-week histology



Stryker Hydroset

BoneSync cement mixed with saline



BoneSync cement mixed with BMA

Results from animal studies are not indicative of clinical use.

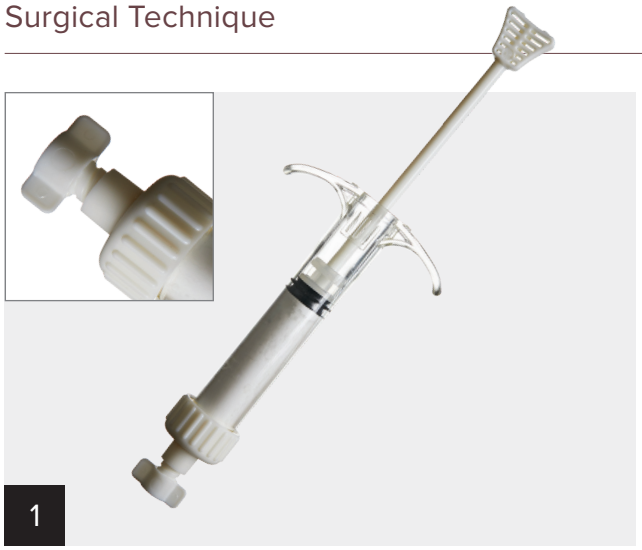
Preparation and Delivery Timeline

1. **Hydrate**
   Start
2. **Mix**
   30 to 45 seconds
3. **Injection/ Working Time**
   4 to 5 minutes
4. **Setting Time**
   6 to 10 minutes

BoneSync™ Cement Kit Package Contents

Pic.	Description
1	Check Valve
2	5 mL Syringe
3	Spindle Drive
4	Mixing Rod
5	Mixing Rod Base
6	Plunger
7	Luer Opening
8	Winged Cap
9	Injection Sleeve
10	Large Cannula, 8.5 ga
11	Small Cannula, 10.5 ga

Surgical Technique



1

Lightly tap syringe to loosen powder. Remove winged cap after filling the liquid syringe. This reduces the risk of powder loss or introduction of undesired moisture while the liquid syringe is being filled.

3 cc Device

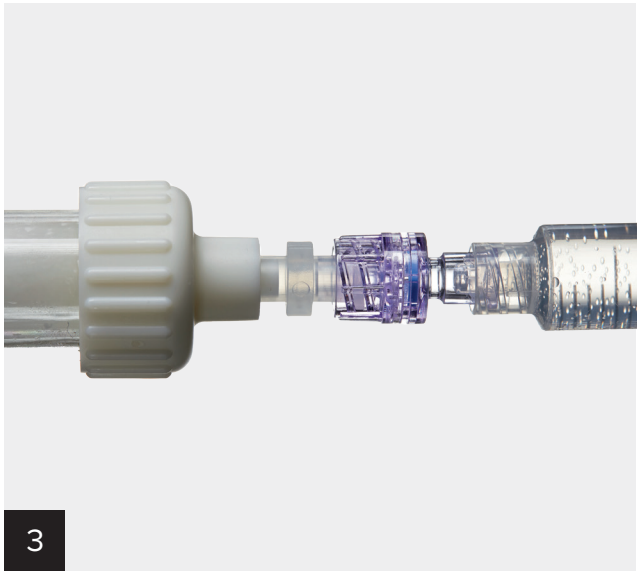
Liquid	Faster Setting	Facilitated Mixing
Saline	2.6 cc	2.8 cc
Blood/BMA	2.7 cc	2.8 cc

5 cc Device

Liquid	Faster Setting	Facilitated Mixing
Saline	3.8 cc	4 cc
Blood/BMA	4 cc	4.2 cc

2

Fill the empty syringe with fluid to the appropriate volume and attach to opposing end of the check valve. The facilitated mixing volumes may be used to ensure the material is easier to fully mix. These volumes may result in slightly longer setting times than the faster setting volumes. The faster setting volumes provide a faster set time but may be slightly more difficult to mix.



3

Attach the white end of the purple check valve to the opening of the powder syringe. Twist clockwise until a firm fit is achieved.

4

Inject liquid into the powder syringe via the check valve.

Note: Do not remove the check valve from the powder syringe.

Draw back the plunger after adding the liquid. Twist the plunger left and right while pushing distally until the mixing rod is fully seated in the cap (should take approximately 5 to 10 seconds). Slowly grind the mixture into the cap to ensure the mixing is thorough.

Twist and pull the mixing rod proximally in the same fashion for approximately 5 seconds until the rod reaches the black plunger.

Note: If you hear a high-pitched noise from the check valve, it is an indication that the injection pathway is clear.

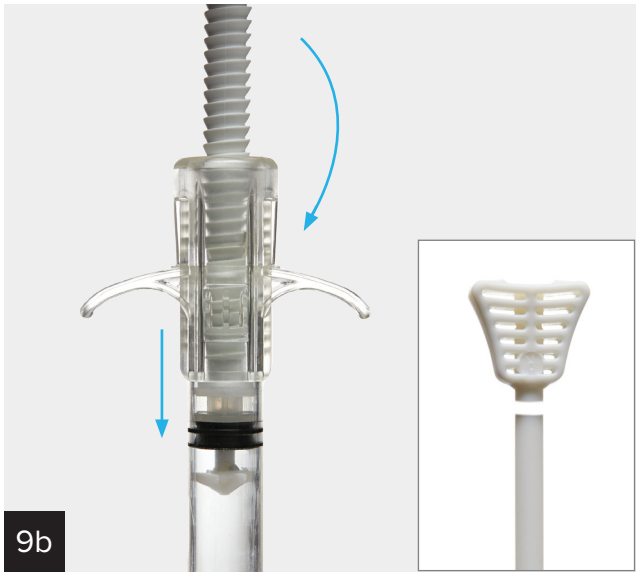
Repeat pumping back and forth for 20 to 30 seconds then remove the check valve. BoneSync™ cement is ready to be injected when the fluid and powder components are homogeneously mixed.

Note: Do not leave solution in the syringe for more than 3 minutes after mixing.

Attach the desired cannula to the opening of the mixing syringe. Pull and twist the mixing rod proximally to the end of the syringe.

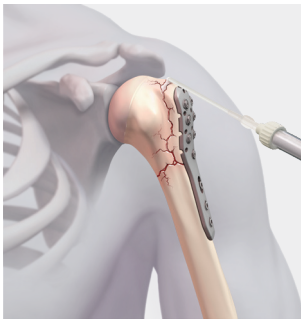
Note: Injection sleeve cannot be attached if mixing rod is not pulled back entirely.

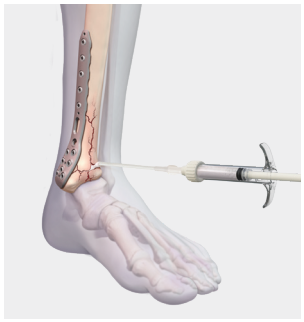
Manual Injection Option
Attach the injection sleeve onto the mixing plunger. (If sleeve is difficult to attach, pull and twist until it becomes flush with the black plunger.) Inject material to the desired clinical area.

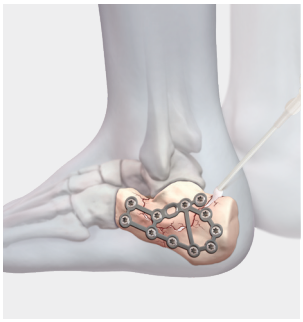


Assisted (Spindle Drive)
Snap off the triangular top piece of the mixing rod. Slide the spindle drive over the mixing rod shaft at the back of the syringe, and press the spindle drive down until it snaps into place. Twist the spindle drive clockwise to inject the mixed cement.

Indications for Use







- BoneSync™ cement is indicated to fill bony voids or gaps of the skeletal system (ie, extremities and pelvis). These defects may be surgically created or osseous defects from traumatic injury to the bone.
- BoneSync cement is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.
- When cured in situ, BoneSync cement provides an open void/gap filler that can augment provisional hardware (eg, K-wires, plates, screws) to help support bone fragments during the surgical procedure.
- The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.
- BoneSync cement resorbs and is replaced by bone during the healing process.

Ordering Information

Product Description	Item Number
BoneSync™ Cement, 3 cc	ABS-**3103**
BoneSync Cement, 5 cc	ABS-**3105**
BoneSync Cement, 10 cc (two 5 cc kits)	ABS-**3105-2**

Products advertised in this brochure/surgical technique guide may not be available in all countries. For information on availability, please contact Arthrex Customer Service or your local Arthrex representative.

References

1. Matsumoto T, Mifune Y, Kawamoto A, et al. Fracture induced mobilization and incorporation of bone marrow-derived endothelial progenitor cells for bone healing. *J Cell Physiol.* 2008;215(1):234-242. doi:10.1002/jcp.21309
2. Arthrex, Inc. Data on file (BoneSync calcium phosphate cement technical review [OF1-000006-en-US]). Naples, FL; 2018.

Arthrex®

This description of technique is provided as an educational tool and clinical aid to assist properly licensed medical professionals in the usage of specific Arthrex products. As part of this professional usage, the medical professional must use their professional judgment in making any final determinations in product usage and technique. In doing so, the medical professional should rely on their own training and experience, and should conduct a thorough review of pertinent medical literature and the product's directions for use. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level and/or outcomes.

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