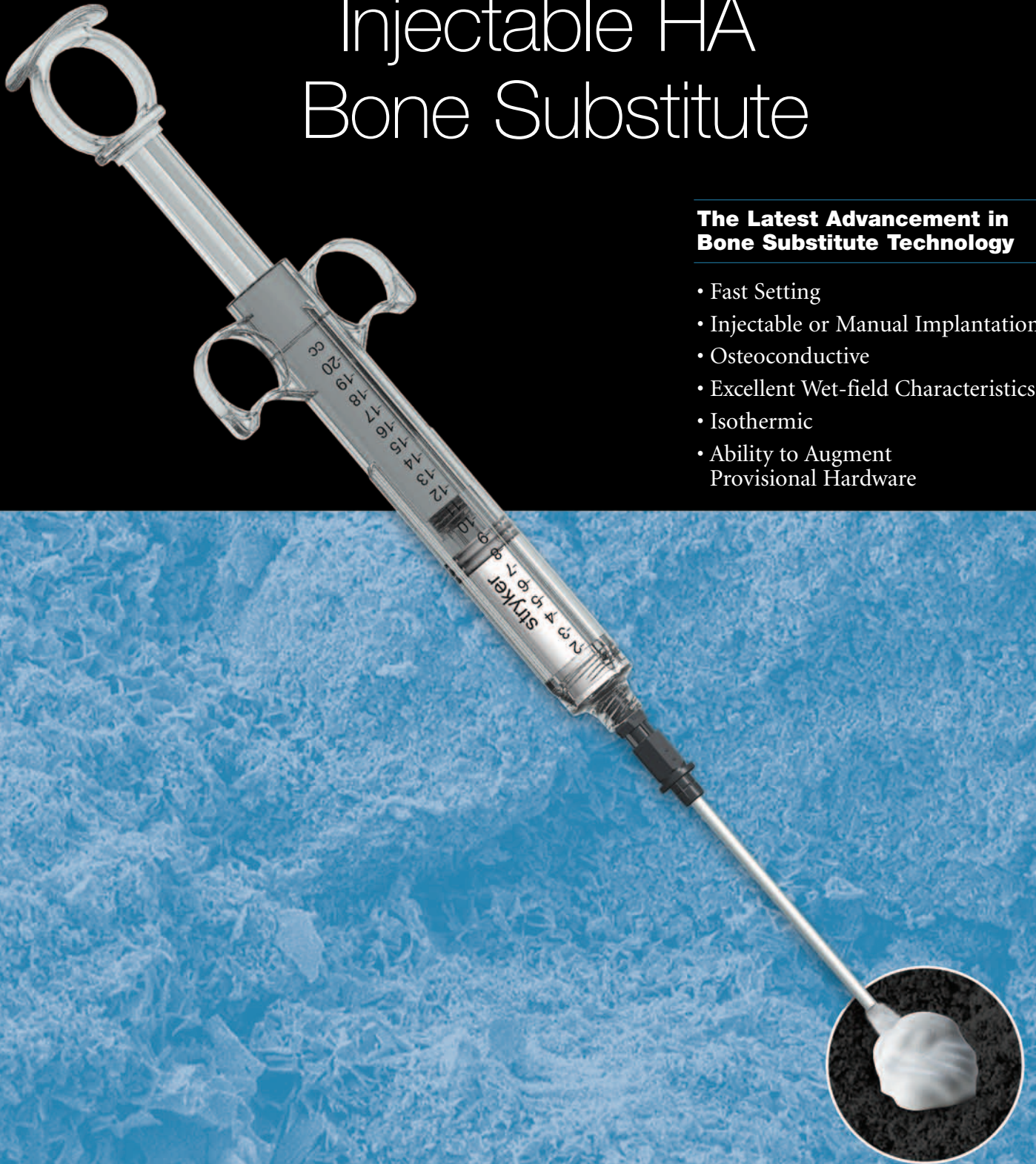


# HydroSet™

## Injectable HA Bone Substitute



### **The Latest Advancement in Bone Substitute Technology**

- Fast Setting
- Injectable or Manual Implantation
- Osteoconductive
- Excellent Wet-field Characteristics
- Isothermic
- Ability to Augment Provisional Hardware

# HydroSet™

## Injectable HA Bone Substitute

The Latest Advancement in  
**Bone Substitute Technology**

### Introduction

HydroSet™ represents the next generation in bone substitute technology intended for a wide variety of clinical applications in multiple surgical specialties.

### Design Rationale and Basic Science

HydroSet™ is an injectable, sculptable and fast-setting bone substitute. HydroSet™ is a calcium phosphate cement that converts to hydroxyapatite, the principle mineral component of bone. The crystalline structure and porosity of HydroSet™ makes it an effective osteoconductive and osteointegrative material, with excellent biocompatibility and mechanical properties<sup>1</sup>. HydroSet™ was specifically formulated to set in a wet field environment and exhibits outstanding wet-field characteristics.<sup>2</sup> The chemical reaction that occurs as HydroSet™ hardens does not release heat that could be potentially damaging to the surrounding tissue. Once set, HydroSet™ can be drilled and tapped to augment the placement of provisional hardware during procedure to help support bone fragments. The rate of remodeling is dependant on the size of the defect and the average age and general health of the patient.

### Product Specifications

#### Chemical Composition

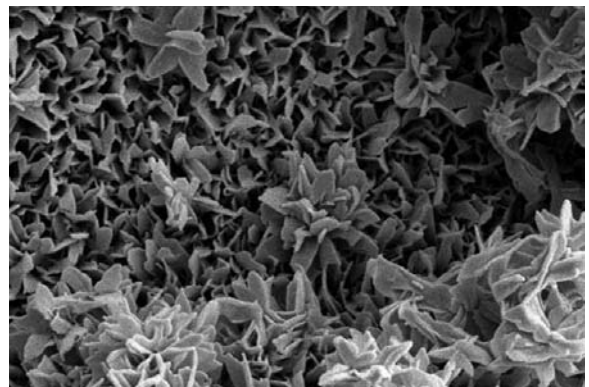
Powder: Dicalcium phosphate dihydrate, Tetracalcium phosphate and Tri-sodium citrate

Liquid: Sodium phosphate, Polyvinylpyrrolidone and water

**Packaging Contains:** Bowl of powder, Liquid-filled syringe, Delivery syringe, Cannula and spatula.

**Shelf Life:** 1 year

**Sterilization:** Ethelyne oxide and Gamma irradiation



Scanning Electron Microscope image of HydroSet™ material crystalline microstructure at 15000x magnification

# Steps to Implantation

## Mixing

Each kit contains one liquid-filled glass syringe and one bowl of powder. Peel back the lid of the bowl and **empty the entire liquid content of the syringe into the bowl of powder** (Fig. 1). Take caution when injecting the liquid into the powder. Loss of liquid may cause a dry mixture that is difficult to inject.

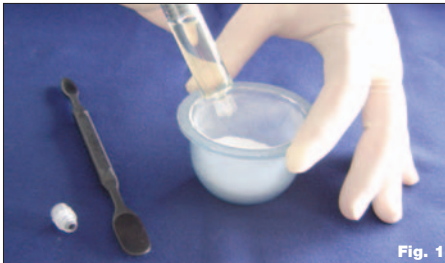


Fig. 1

**Note:** HydroSet™ is a temperature sensitive product. Ideal operating and storage room temperatures should be between 18° and 22° C (64.4° – 71.6°F).

Mix the liquid and powder quickly in a circular motion for 45 seconds, ensuring that all the entire solution has been distributed throughout the powder (Fig. 2). Compress the material against the sides of the bowl until a homogeneous, consistent paste is achieved.

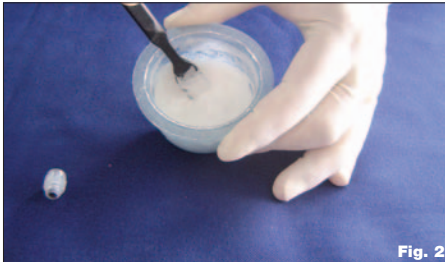


Fig. 2

**Note:** The cement paste may look uniformly mixed after 10-15 seconds of mixing; however, continue to mix for 45 seconds to ensure the powder is thoroughly mixed into the solution. If manual implantation is desired, please proceed to implantation once a homogeneous paste is achieved.

## Transfer Cement To Delivery Syringe

Place the cement delivery syringe barrel at an angled position using the inner blister fixture to aid cement transfer (Fig. 3).

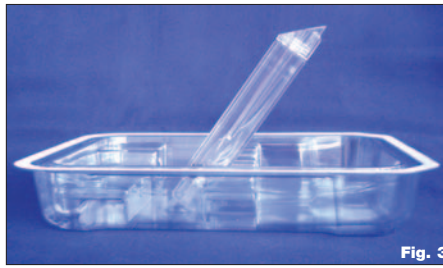


Fig. 3

Transfer the paste from the mixing bowl to the delivery syringe using the supplied spatula (Fig. 4).

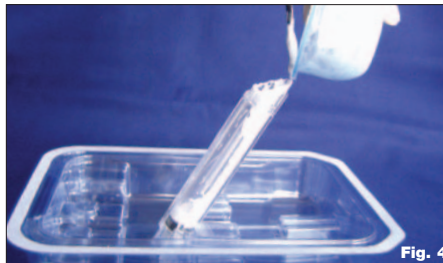


Fig. 4

This will allow the paste to run slowly down the syringe barrel keeping an open air pathway through the syringe assembly at all times.

The funnel comes pre-attached to the syringe barrel. Once cement transfer is complete, remove the funnel by turning counter-clockwise (Fig. 5). Attach the supplied cannula by turning clockwise (Fig. 6).



Fig. 5

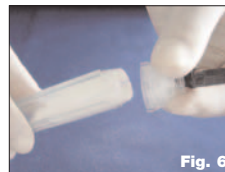


Fig. 6



Fig. 7

Attach the plunger rod into the piston at the syringe barrel entrance by threading into place while keeping the syringe system vertical with the cannula pointing up (Fig. 7).

Load the plunger rod into the back of the syringe barrel by turning clockwise.

Remove trapped air in the syringe assembly and to accumulate the paste to the base of the syringe (Fig. 8).

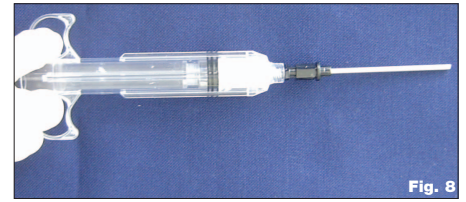


Fig. 8

**Note:** Removing trapped air is essential. Trapped air will compromise injectability.

**Note:** The loading process should be complete by 2 minutes and 30 seconds.

## Implantation & Sculpting

Once the syringe is fully loaded and ready to inject, there will be approximately 2 minutes of injection time before the material begins to set. At this time, the material may become too difficult to inject. Contact and heat transfer between the palm of hands and syringe barrel may decrease the injectability time window.

Deliver the material to the defect site. Use the spatula to further contour the HydroSet™ as desired.

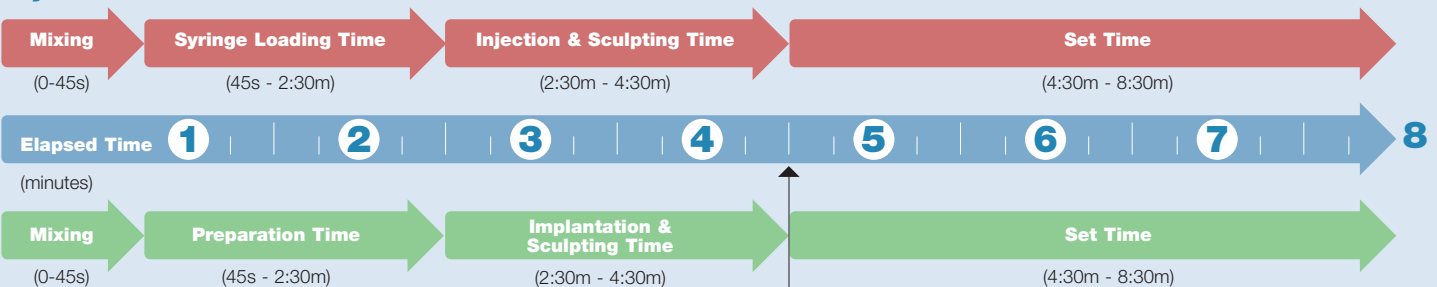
**Note:** Sculpting and material manipulation must cease after 4 minutes and 30 seconds.

## Set Time

Allow the material to set completely before closing. Set time may vary between 8 to 10 minutes from the start of mixing (potentially longer if the defect effective temperature is less than 32° C). Leave the material undisturbed until it is completely set.

**Note:** If the placement of hardware is required, wait until twelve minutes until implantation of K-Wires, plates, or screws.

## Injection

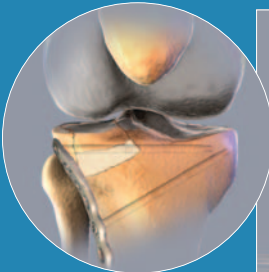
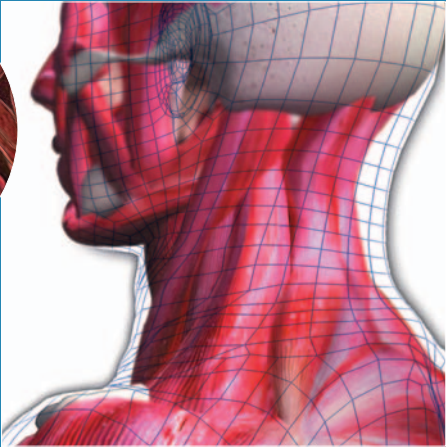


**NOTE:** Sculpting and material manipulation must cease after 4 minutes and 30 seconds.

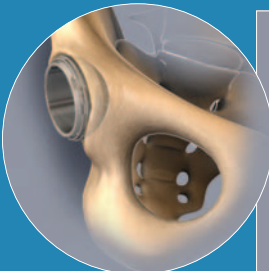
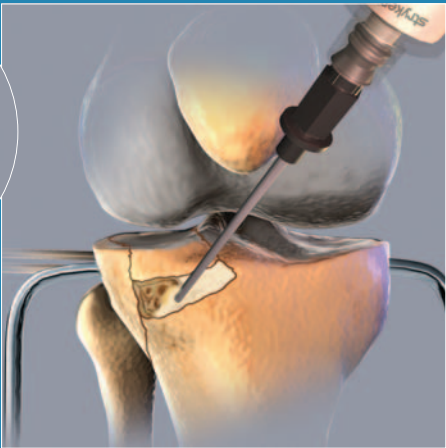
# Indications



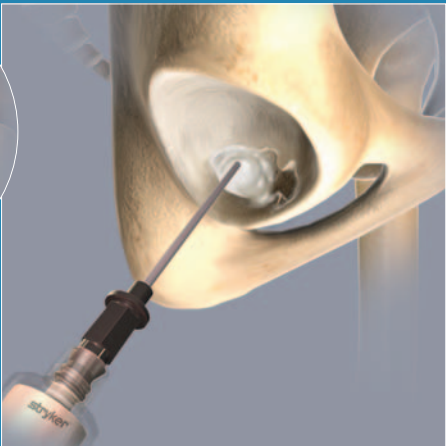
**CMF**



**Trauma**



**Orthopaedics**



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## Indications

HydroSet™ is a self-setting calcium phosphate cement indicated to fill bony voids or gaps of the skeletal system (i.e., extremities, craniofacial, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet™ is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

HydroSet™ cured *in situ* provides an open void/gap filler than can augment provisional hardware (e.g., 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.

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## Advantages

### Injectable or Manual Implantation

HydroSet™ can be easily implanted via simple injection or manual application techniques for a variety of applications.

### Fast Setting

HydroSet™ has been specifically designed to set quickly once implanted under normal physiological conditions.

### Isothermic

HydroSet™ does not release any heat as it sets, preventing potential thermal injury.

### Excellent Wet-Field Characteristics

HydroSet™ is chemically formulated to set in a wet field environment eliminating the need to meticulously dry the operative site prior to implantation.<sup>2</sup>

### Osteoconductive

The composition of hydroxyapatite closely matches that of bone mineral thus imparting osteoconductive properties.<sup>3</sup>

### Augmentation of Hardware

HydroSet™ can be drilled and tapped to accommodate the placement of provisional hardware during the surgical procedure.

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## References

1. Chow, L, Takagi, L. A Natural Bone Cement – A Laboratory Novelty Led to the Development of Revolutionary New Biomaterials. J. Res. Natl. Stand. Technol. 106, 1029-1033 (2001).
2. 1808.E703
3. Dikson, K.F., et al. The Use of BoneSource Hydroxyapatite Cement for Traumatic Metaphyseal Bone Void Filling. J Trauma 2002; 53:1103-1108.

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