

HydroSet

Injectable Bone Substitute

The Difference in
Bone Substitute Technology

- Fast Setting
- Excellent Wet-Field Properties
- Injectable or Manual Implantation
- Osteoconductive
- Isothermic



Introduction

HydroSet

Injectable HA Bone Substitute

The Difference in Bone Substitute Technology

Introduction

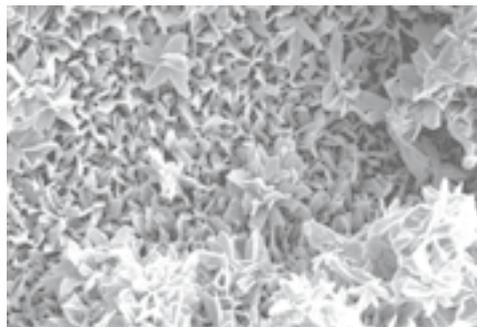
HydroSet represents the next generation in bone substitute technology and is an ideal bone substitute solution for a wide variety of clinical applications in multiple surgical specialties. HydroSet is packaged sterile only.

Design Rationale and Basic Science

HydroSet is an injectable, fast-setting, osteoconductive hydroxyapatite (HA) bone substitute. It is designed to set under normal body wet-field conditions and produces hydroxyapatite as the final product. HA is the principle mineral constituent of bone. The setting reaction is nonexothermic, therefore no potentially damaging heat is released to surrounding tissues. HydroSet was specifically formulated to provide exceptional wet-field environment characteristics.

Its crystalline structure and porosity make HydroSet a highly effective bone substitute with excellent biocompatibility and mechanical properties. This product easily injects through a small gauge cannula to reliably fill irregular voids. HydroSet promotes bony in-growth and provides an x-ray visible, osteoconductive scaffold with optimized properties for filling skeletal defects. Its makeup and structure encourage remodeling via osteoclastic, cell-mediated resorption to form healthy new bone. (Fig. 1)

The actual rate of remodeling and resorption are dependent upon the size of the defect, age and general health of the patient. HydroSet was designed to be durable and stable, and will maintain its shape, volume and position over time.



(Fig. 1)

Scanning Electron Microscope Image of HydroSet displaying a crystalline microstructure at 15000x magnification

Implant Instructions

Mixing

Step I

Each kit contains one liquid filled glass syringe and one bowl of powder. Peel back the lid on the bowl; empty the liquid contents of the syringe into the bowl with powder. (Fig. 1)

Caution shall be taken when injecting, so as not to lose liquid. Not injecting liquid solution into the powder could cause a dry mixture that is difficult to inject.

NOTE: HydroSet is a temperature sensitive product with ideal operating and storage room conditions being in the range of 18° – 22°C (64° – 72°F).

Step II

Mix the liquid and powder quickly in a circular motion for 45 seconds, ensuring that all the solution has been distributed throughout the powder. Compress the material against the sides of the bowl until a homogeneous, consistent paste is achieved. The cement paste may look uniformly mixed after 10 – 15 seconds of mixing; however, continue to mix for 45 seconds to ensure powder is thoroughly mixed into solution. (Fig. 2)

NOTE: Minimize contact and heat transfer between palm of hands and bowl of cement, as excessive heat will influence time window.

If manual implantation is desired, please proceed to Step IV B. once a homogenous paste is achieved.

Transfer cement to delivery syringe

Step III

Place the cement delivery syringe with pre-attached funnel at an angled position using the holding post of the inner blister tray to aid cement transfer.

Transfer the cement from the mixing bowl to the cement delivery syringe using the supplied spatula. (Fig. 3)

Once cement transfer is complete, remove the pre-attached funnel from the end of the cement delivery syringe (counter clockwise direction).



(Fig. 1)



(Fig. 2)



(Fig. 3)



(Fig. 4)



(Fig. 5)



(Fig. 6)

Attach the supplied cannula to the end of the cement delivery syringe (clockwise direction). (Fig. 4)

Attach the plunger rod into the plunger at the syringe barrel entrance by screwing into place while keeping the syringe system vertical with the cannula pointing up. (Fig. 5)

Care shall be taken to facilitate an air pathway throughout syringe assembly at all times to allow air to escape through the cannula system when loading the syringe plunger rod.

Fully load the plunger rod into the syringe barrel to remove trapped air within the syringe assembly and to accumulate the cement at the base of the syringe so that it is ready for implantation. Removing trapped air is necessary, as trapped air will compromise injectability. (Fig. 6)

The loading process should be finished by 2 minutes 30 seconds, from time 0.

Implantation and Sculpting

Step IV

A. Injection of HydroSet

Implantation should be completed by 4 minutes 30 seconds from the start of mixing as the fast setting nature of the cement could restrict the injectability of the cement after this time point.

NOTE: Minimize contact and heat transfer between palm of hands and syringe barrel with cement within, as excessive heat will reduce the injectability time window.

NOTE: Prior to injection, control active bleeding at the implant site. Suction, cautery, bone wax, and gel foam may be used. Inject the material to the site using the syringe provided.

Implant Instructions / Ordering Information

Step IV (continued)

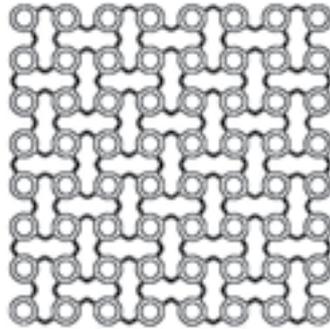
B. Manual Implantation of HydroSet

Use the spatula or hand to implant / contour as desired. In defects with exposed surface areas larger than 4 cm², place supportive metal implants (titanium mesh) prior to applying the material. (Fig. 7)

Recommendation: For best results and optimal cement properties wait until 2 minutes and 30 seconds after the start of mixing to implant the material.

NOTE: Prior to implantation, control active bleeding at the implant site. Suction, cautery, bone wax, and gel foam may be used.

NOTE: The insertion of fixation implants (e.g. K-wires, screws) after hardening is possible, but deviations from the guidelines prescribed in the Instructions For Use may result in the fracture of the HydroSet material.



(Fig. 7)

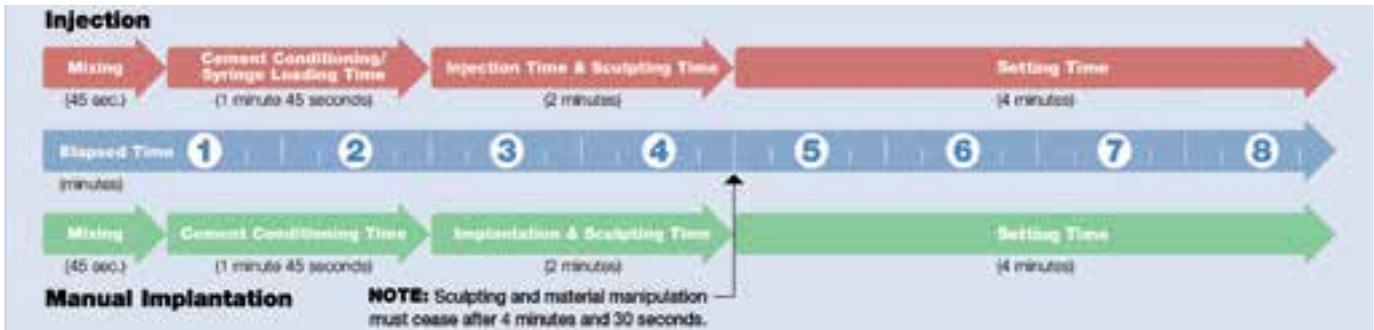
Step V

Allow the material to set completely. Setting time may vary between 8 to 10 minutes from the start of mixing (potentially longer if the effective temperature at the defect is less than 32° C). Leave the material undisturbed during setting time.

Step VI

Close the surgical site. In defects with a surface area greater than or equal to 4 cm², apply a suction drain to prevent excessive wound fluid accumulation.

NOTE: Times listed in the chart below (Fig. 8) depend on storage and OR temperatures. Ideal OR and storage temperatures should be between 18° and 22° C (64° – 72° F).



(Fig. 8)

HydroSet Ordering Information

HydroSet is packaged sterile only



Shelf Life

2 years

Sterilization

Ethylene Oxide and Gamma Irradiation

REF

Description

79-43903

3cc, HydroSet Injectable Cement (6.75 g)*

79-43905

5cc, HydroSet Injectable Cement (10.5 g)*

79-43910

10cc, HydroSet Injectable Cement (19.75 g)*

79-43915

15cc, HydroSet Injectable Cement (29.05 g)*

*All HydroSet products include a cement delivery syringe with cannula (length 13 cm, diameter 10 ga).

Indications

Indications and Advantages

Indications for Use

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 that 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.

HydroSet is a self setting calcium phosphate cement intended for use in the repair of neurosurgical burr holes, contiguous craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

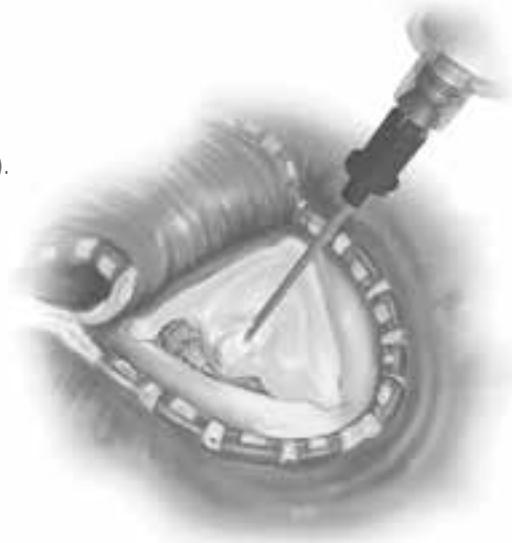
Hydroset is a self-setting calcium phosphate cement intended to enhance screw fixation in cancellous bone at and after surgery. Not intended for use in areas where the surrounding bone is osteoporotic, avascular or otherwise not capable of supporting or anchoring the implant.

Contraindications

HydroSet is not designed or sold for any use except as indicated. This product is not cleared for use in Vertebroplasty or Kyphoplasty. Do not use HydroSet in the presence of any contraindication.

Contraindications include but are not limited to:

- Use in a currently infected field or surgical site near an infection.
- Use for stress bearing applications (for example, mandibular segment replacement).
- Use in areas where surrounding bone is avascular or is incapable of supporting or anchoring the implant.
- Use in patients with the following: abnormal calcium metabolism, metabolic bone disease, a recent untreated infection, immunologic abnormalities and systemic disorders which result in poor wound healing or will result in tissue deterioration over the implant site.
- Use in patients who have not reached an age at which skeletal system growth is essentially complete.
- Use in patients with acute traumatic injuries with open wounds near the defect that are likely to become infected.
- Use in patients with open fractures.
- Use in patient with fractures or voids that link joint spaces and/or articulating surfaces.



Advantages

• **Excellent Wet-Field Characteristics**

The HydroSet material is chemically formulated to harden in a wet-field environment eliminating the need to meticulously control moisture at the operative site.

• **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, potentially minimizing procedure time.

• **Isothermic**

HydroSet prevents thermal injury as it does not give off any potentially damaging heat when it hardens.

• **Osteoconductive**

HydroSet is a calcium phosphate cement that hardens to form hydroxyapatite and remodels to natural bone through osteoclastic resorption and new bone formation.

• **Radiopaque**

The HydroSet material is easy to visualize post-operatively.

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