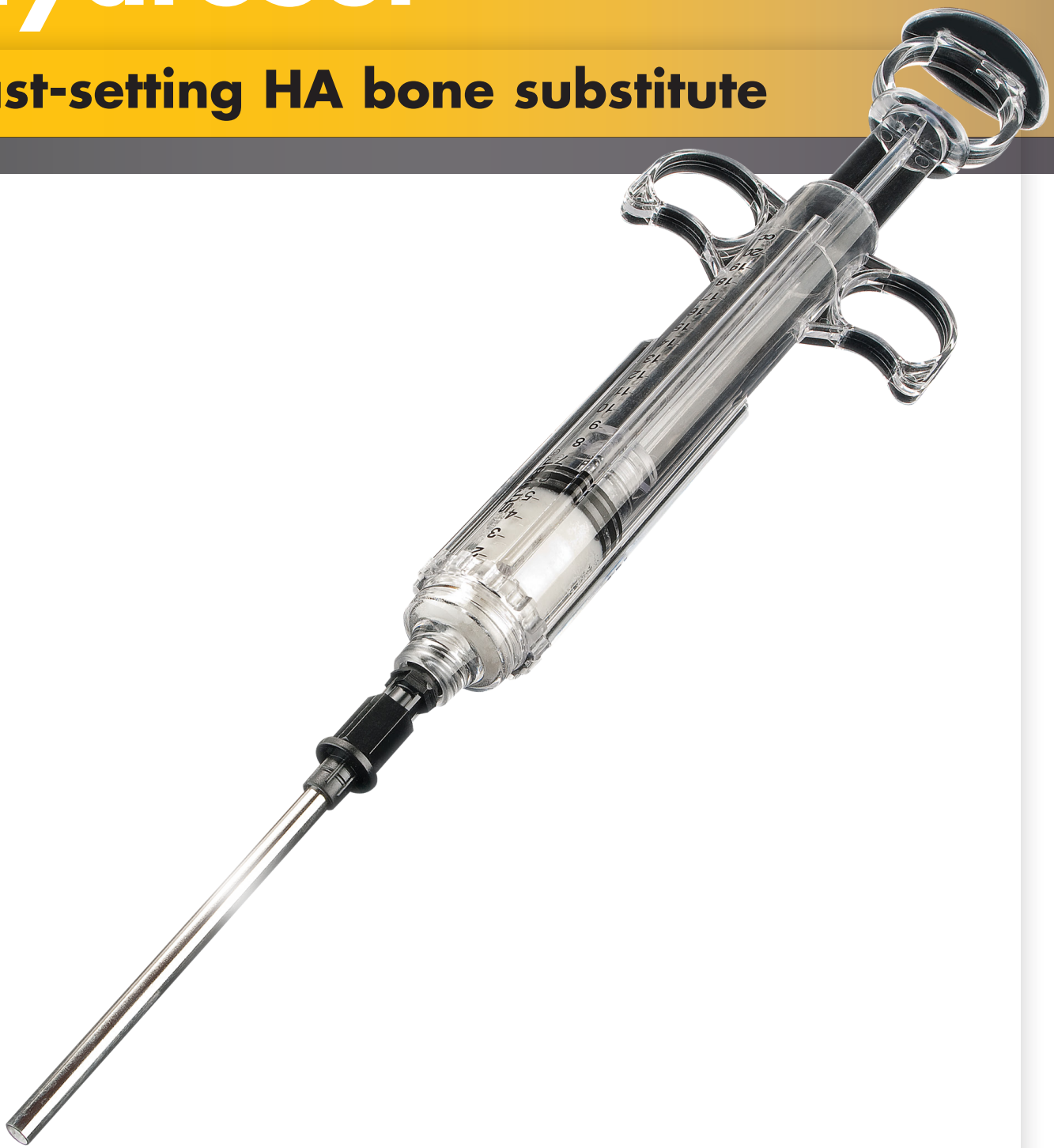
stryker

HydroSet®

Fast-setting HA bone substitute



Features

The HydroSet material is formulated to harden in a wet field environment.

- Fast-setting[1]
- Excellent wet-field properties[2,3]
- Injectable or manual implantation[4]
- Osteoconductive[1]
- Isothermic[1]

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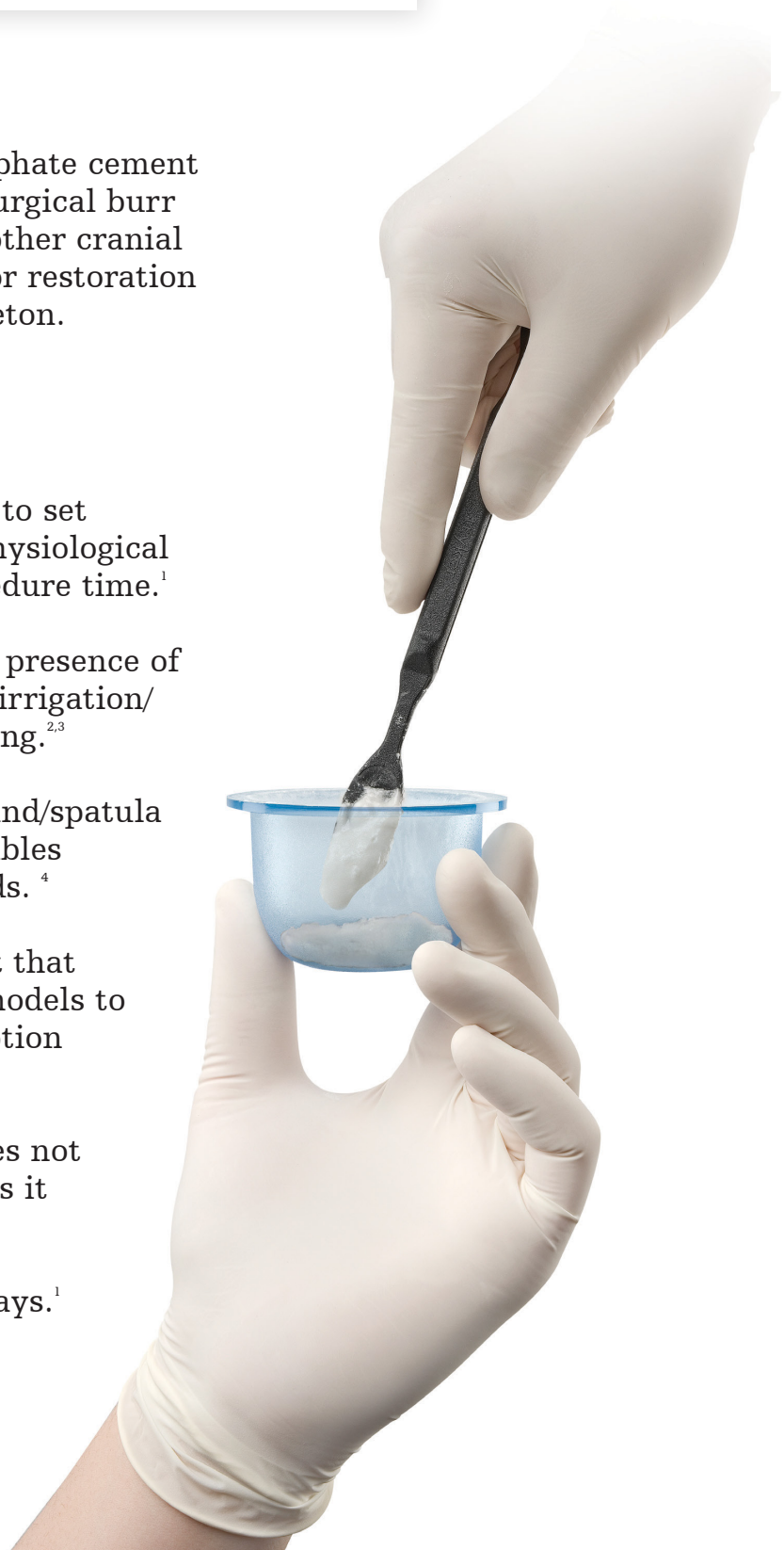
Fast-setting HA bone substitute

Indications

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.



Features and benefits

Fast-Setting
HydroSet has been specifically designed to set quickly once implanted under normal physiological conditions, potentially minimizing procedure time.[1]

Excellent Wet Field Characteristics
HydroSet is formulated to harden in the presence of water, blood, and CSF, which allows for irrigation/wash out of the surgery site during setting.[2,3]

Injectable or Manual Implantation
HydroSet can be applied manually by hand/spatula or injected through a syringe, which enables users to better meet unique closure needs. [4]

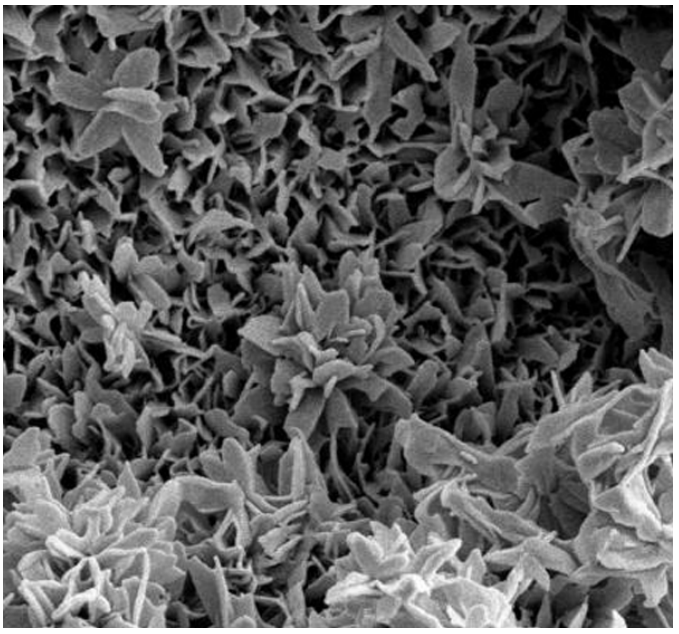
Osteoconductive
HydroSet is a calcium phosphate cement that hardens to form hydroxyapatite and remodels to natural bone through osteoclastic resorption and new bone formation.[1]

Isothermic
HydroSet avoids thermal injury as it does not give off any potentially damaging heat as it hardens.[1]

Radiopaque
HydroSet is visible on postoperative X-rays.[1]

Proven bone substitute technology
for over a decade

Hydroset is part of Stryker's market leading bone cement portfolio and is an excellent substitute solution for a wide variety of clinical applications in multiple surgical specialties.[2]



Scanning Electron Microscope image of HydroSet material crystalline microstructure at 15000x magnification[2]

Ordering information

Part number	Description	Qty
79-43903	HydroSet Bone Cement	3cc
79-43905	HydroSet Bone Cement	5cc
79-43910	HydroSet Bone Cement	10cc
79-43915	HydroSet Bone Cement	15cc

Implantation instructions

1 Add liquid to powder. 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.

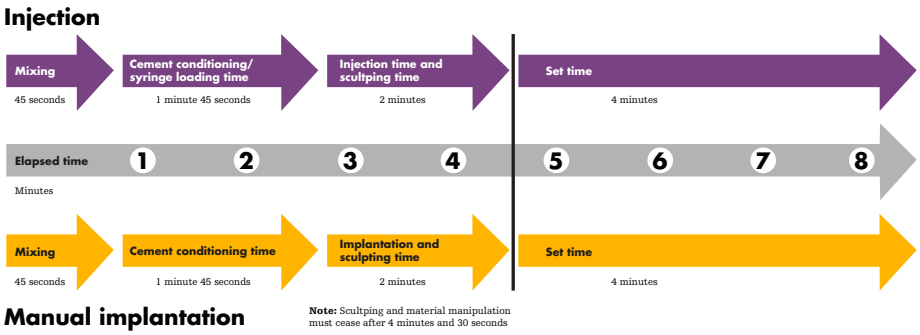
2 Mix liquid and powder. Mix the liquid and powder quickly (3-4 revolutions per second) in a circular motion for 45 seconds, ensuring that all the solution has been distributed throughout the powder. Compress the material against the sides of the bowl until a homogeneous, consistent paste is achieved.
Note: 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 intosolution. Care should be taken when handling and mixing the powder in the bowl. Losing powder could cause a wet cement mixture that may exhibit undesirable handling and setting characteristics.

3 Transfer cement to delivery syringe. Place the cement delivery syringe barrel at an angled position using the fixture aid in the blister tray to hold the syringe securely.
Note: Approach the fixture aid holding the syringe at a 45º angle and then push the syringe onto the fixture aid to achieve a stable footing.
Transfer the cement from the mixing bowl to the cement delivery syringe using the supplied spatula. The funnel comes pre-attached to the syringe barrel. Once cement transfer is complete, remove the funnel from the end of the cement delivery syringe barrel (counter clockwise direction). Attach the supplied cannula to the end of the cement delivery syringe barrel (clockwise direction). Attach the plunger rod into the piston at the syringe barrel entrance by screwing into place while keeping the syringe system vertical with the cannula pointing up (clockwise direction). Now position the delivery syringe in a vertical position with the cannula pointing up and fully load the plunger rod into the syringe barrel to remove trapped air within the syringe assembly and to accumulate the cement to the base of the syringe ready for implantation.
Note: Removing trapped air is necessary, as trapped air will compromise injectability.

4 The loading process should be finished by 2 minutes 30 seconds from the start of mixing. Implantation and sculpting the cement; Prior to implantation, it is important to check for the desired cement consistency for times greater than or equal to 2 minutes 30 seconds after initial mixing. Cement should ideally be fully injected by 4 minutes 30 seconds from the start of mixing. After implantation, cement sculpting past 4 minutes 30 seconds from the start of mixing may disrupt the setting properties of the cement.
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. In defects with exposed surface areas larger than 4cm^2, place supportive metal implants (titanium mesh) prior to applying the material.
Note: Prior to injection, control active bleeding at the implant site. Suction, cautery, bone wax, and gel foam may be used.
Warning: Remove gel foam and bone wax prior to implantation.

5 Allow the material to set completely. Set time will occur between 4 minutes 30 seconds to 8 minutes 30 seconds from the start of mixing (potentially longer if the temperature at the defect site is below 32ºC). Leave the material undisturbed during the setting time. Close the surgical site. In defects with a surface area greater than or equal to 4cm^2, apply a closed suction drain to prevent excessive wound fluid accumulation.

Note: HydroSet is a temperature sensitive product with ideal product and operating room temperatures being in the range of 18°-22° C (64.4° – 71.6° F). Product use below this temperature range will result in a runnier paste consistency and during injection could cause liquid to powder separation. Product use above this temperature range will result in a stiffer paste with reduced working and injectability time.



Craniomaxillofacial

This document is intended solely for the use of healthcare professionals. 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.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets.

Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

References:
1. Larsson, S.: Injectable Phosphate Cements – A Review. 2006.
2. Hannink, G., Wolke, J.G.C., Schreurs, B.W., Buma, P.: In Vivo Behavior of a Novel Injectable Calcium Phosphate Cement Compared with Two Other Commercially Available Calcium Phosphate Cements. 2007.
3. HydroSet IFU
4. Clarkin, O.M., Boyd, D., Madigan, S., and Towler, M.R.: Comparison of an Experimental Bone Cement with a Commercial Control, HydroSet, 2009.

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