

stryker®

Lower Extremity Fixation

with **HydroSet™**

Surgical Technique



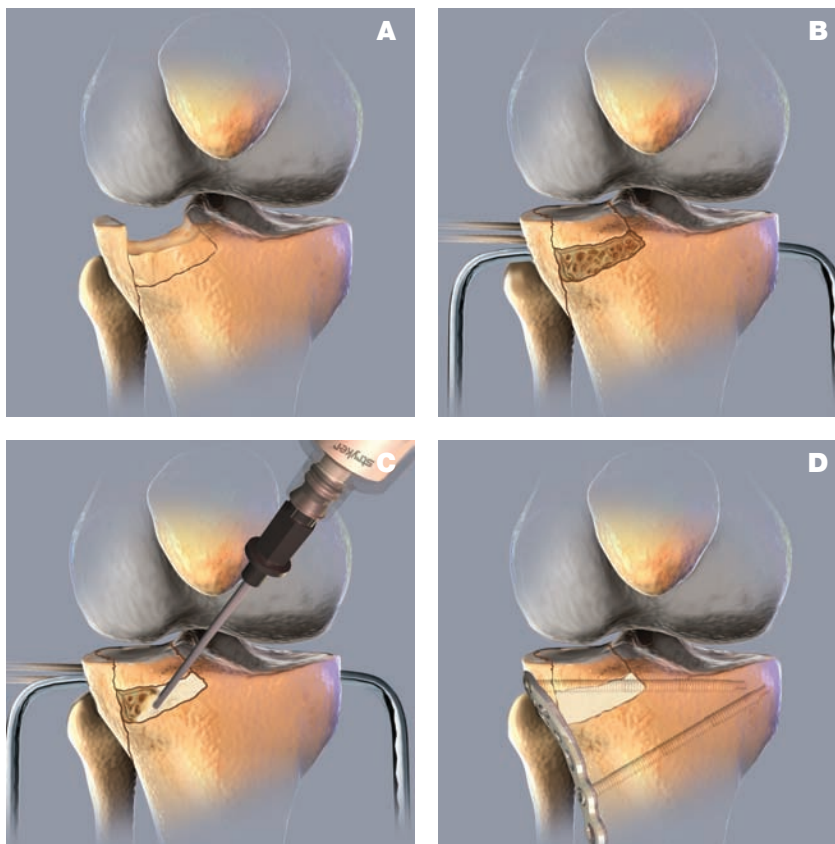
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1. **Obtain anterolateral exposure** with partial elevation of tibialis anterior muscle. Submeniscal arthrotomy may be useful for direct joint visualization of the articular surface (optional).

2. **Reduce the articular surface:**

- Option 1- Direct elevation of depressed articular fragments, visualized through the wedged open split fragment.
 - Option 2- Indirect elevation of depressed articular fragments through cortical window (medial or lateral).
- Temporary fixation with K-wires may be helpful in stabilizing the elevated articular fragments until HydroSet™ Bone Substitute or definitive hardware is placed.



In preparation for use, thoroughly mix the liquid and powder (HydroSet™) for 45 seconds.

Note: Perform either Step 3 or Step 4

3. **Inject the HydroSet™** using the provided syringe and cannula directly into the residual defect. Close the split fragment. After the cement has set, place the definitive hardware.

OR

4. **Place the hardware and inject the HydroSet™** using the provided syringe and cannula under fluoroscopic guidance. The cannula may be inserted through an exposed fracture line or a 3.5mm drill hole. The HydroSet™ is then injected under fluoroscopic control to minimize extrusion outside of the defect.

HydroSet™ Injectable HA Bone Substitute

Trauma Ordering Information

Ref	Description
397003	3cc HydroSet™ Bone Substitute
397005	5cc HydroSet™ Bone Substitute
397010	10cc HydroSet™ Bone Substitute
397015	15cc HydroSet™ Bone Substitute



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- 1. Obtain exposure of the distal tibia.**
Anterolateral or anteromedial exposures are standard.
- 2. Obtain preliminary reduction of the articular surface.** K-Wires are useful to temporarily maintain articular reduction. Reduction can be obtained by direct manipulation of the depressed fragments or indirectly by the use of tamps and elevators placed through cortical windows.

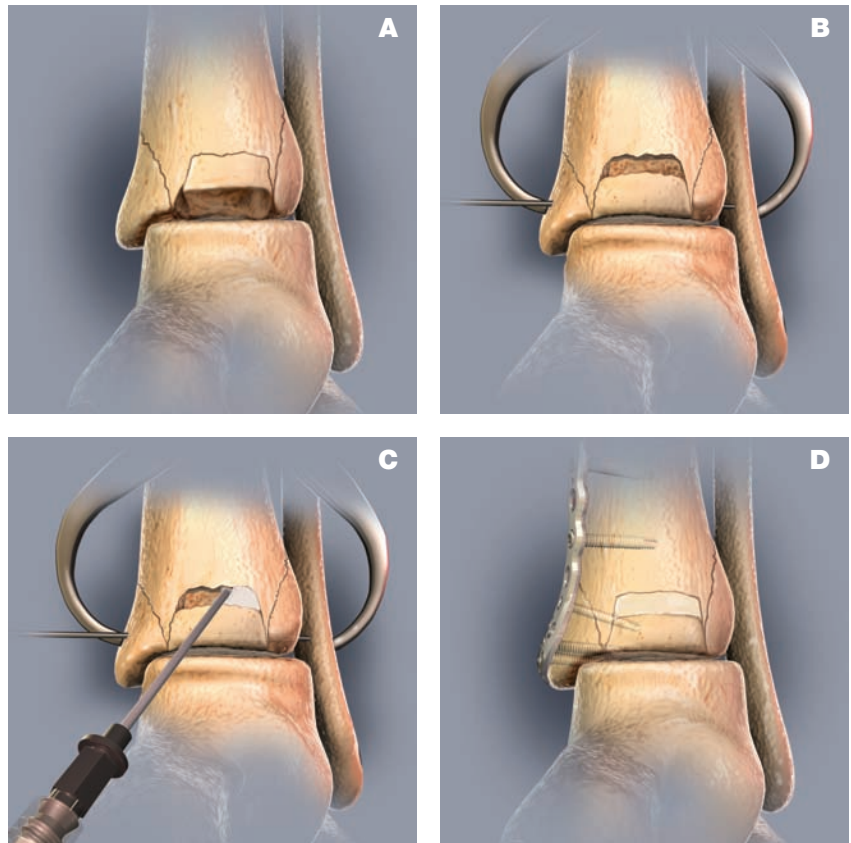
In preparation for use, thoroughly mix the liquid and powder (HydroSet™) for 45 seconds.

Note: Perform either Step 3 or Step 4

- 3. Inject the HydroSet™** using the provided syringe and cannula directly into the residual defect. After the HydroSet™ has set, follow with placement of definitive hardware.

OR

- 4. Place the definitive hardware and inject the HydroSet™** using the provided syringe and cannula under fluoroscopic guidance. The cannula may be inserted through an exposed fracture line or a 3.5mm drill hole. The HydroSet™ can be injected under fluoroscopic control to minimize extrusion outside of the defect.



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Indications for Use

HydroSet™ is 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. The 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.

Important Information

Read and understand all the information in these instructions. If you have any questions, contact one of the following:

1. Stryker Orthopaedics sales representative or Customer Service at 269-324-5346
2. Stryker Craniomaxillofacial sales representative or Customer Service at 1-800-962-6558 or 877-534-2464

WARNINGS

- For optimal mixing, prepare HydroSet™ in batches of 15cc or less.
- HydroSet™ is a single use device. Do not attempt to re-sterilize or use leftover material.
- Use HydroSet™ within sixty minutes after opening the package. It must be applied to the surgical site immediately after mixing and/or transferring to the delivery syringe.
- Exposure to humidity prior to mixing will compromise results.
- The safety and effectiveness of HydroSet™ is not known when used in patients who have undergone or who are to undergo radiation therapy at or near the implant site.
- The safety and effectiveness of HydroSet™ when combined with bone, muscle grafts, dura fascia, abdominal fat, acrylic, silicone or Dacron® is not yet established.
- The safety and effectiveness of HydroSet™ in defects that would result in intradural placement is not known.
- Mix materials into a consistent, homogeneous paste prior to implantation, strictly avoiding implantation of unmixed or dry particles.
- Do not manipulate site during intraoperative set time.
- Meticulously remove all mucosa where contact is expected between HydroSet™ and mucosa within the sinus cavities.
- The insertion of fixation implants after hardening may fracture the HydroSet™ material.
- Inject the entire liquid solution from the syringe into the powder; caution should be taken when injecting so as to not lose liquid. Not injecting all liquid solution into the powder could cause a dry mixture.
- 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.
- Avoid extended cement working time outside the defect site as the fast setting nature of the cement could impart undesirable shaping or filling of defect characteristics.
- Care should be taken if irrigating the defect site to keep clean; over irrigating could cause the cement to washout or lose dimensional stability during the setting period.
- The cement setting time is sensitive to temperature; delayed setting times should be expected if the effective defect site temperature is much lower than standard body temperature (37° C or 98.6° F).
- The cement setting time is sensitive to defect size; delayed setting times should be expected if the defect site requires more than 15cc of cement.
- The cement should be set at the defect site before closing; premature closing may cause cement washout.
- Care should be taken when closing the flap at the defect site to not disrupt the cement setting and stability of the implant.
- The device should be used only by trained and skilled healthcare professionals.

For U.S. Distribution Only

The information presented in this brochure is intended to demonstrate the breadth of Stryker product offerings. Always refer to the package insert, product label and/or user instructions before using any Stryker product. Surgeons must always rely on their own clinical judgment when deciding which treatments and procedures to use with patients. Products may not be available in all markets. Product availability is subject to the regulatory or medical practices that govern individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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- The effect of HydroSet™ on patients with the following is not known:
 - Documented renal disease
 - Metabolic bone disease
 - Pregnancy/nursing
 - Defects due to disease or congenital malformation
 - Cardiovascular disease precluding elective surgery
 - Infection during the last three months and/or a history of chronic infection.
 - HydroSet™ should only be prepared with the liquid solution. The effects of preparing HydroSet™ with any other substance, including antibiotics and blood, are not known.
 - The effect of layering HydroSet™ is not known. Placement over inadequate or nonvascularized tissues or allograft material is not recommended.
 - In defects with a surface area greater than 4cm², closed suction drainage is recommended to prevent wound fluid accumulation during the immediate post-operative period. Excess fluid can cause HydroSet™ to malfunction (for example, thin and dissolve prior to setting).
 - Reinforcement with metal mesh or implants should be considered for defects with a surface area greater than 4cm² or covering a convexity.
 - Aseptic handling techniques are required during all phases of device handling.
 - The device should be implanted only in a sterile field.
 - Successful results may not be achieved in every surgical case. Additional surgery to remove or replace the implant may be required, at any time, due to medical reasons or device failure. If corrective action is not taken, complication may occur.
 - Federal law (USA) restricts this device to sale by or on the order of a physician.
- Dacron® is a registered trademark of E. I. du Pont de Nemours and Company.

Contraindications

HydroSet™ is not designed or sold for any use except as indicated. 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 skull and facial growth is essentially complete.
- Use in patients with acute traumatic injuries with open wounds near the defect, which are likely to become infected.
- Use in patients with open fractures.
- Use in patients with fractures or voids that link joint spaces and/or articulating surfaces.

Possible Complications

The occurrence of any of the following complications is possible and may require re-operation and/or removal of the implant:

Complications may include but are not limited to:

- Tissue thinning over the implant site
- Tenderness, redness, edema
- Seroma, hematoma or infection
- Swelling, fluid collection
- Loss of contour
- Implant fracture, migration

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