stryker®

Interventional Pain

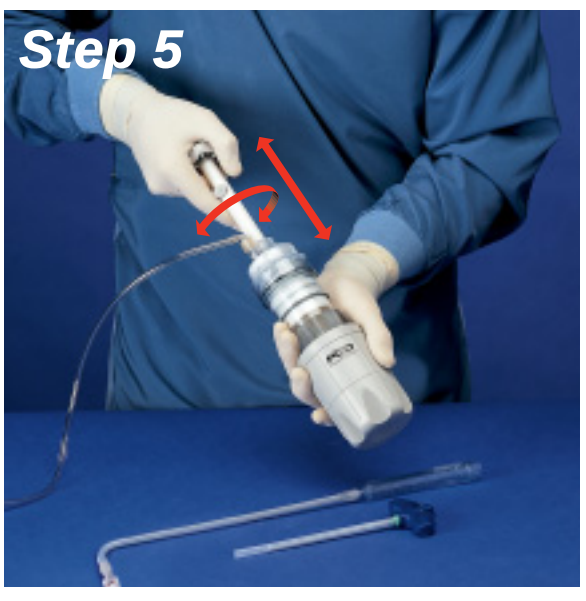
PCD & SpinePlex
Cement Mixing & Delivery

Optional: Connect luer end of tubing to mixing handle and the open end to a vacuum source. Set pressure of nitrogen tank to 70-90 psi. Activate hand or foot pump until 22 mmHg when mixing cement, or activate wall suction at medium pressure when mixing cement.

Luer lock the delivery cartridge to the extension tube. The stationary end should lock onto the delivery cartridge.

Place funnel on mixing chamber and pour bone cement powder followed by the chilled liquid monomer into the mixing chamber.

Remove funnel from mixing chamber and thread mixing head on mixing chamber in a clockwise fashion until it locks.



Mix cement in an up and down motion rotating the mixing handle at the top and bottom of the mixing chamber for 60 seconds.

Detach handle by pulling it to the top of the mixing chamber and pushing the gray button inward and rotating clockwise. Pull handle straight up out of the mixing chamber.

Lock the delivery cartridge with the extension tube attached **counter-clockwise** onto the mixing chamber.

Transfer and prime extension tube by turning gray base of mixing chamberclockwise until cement reaches the end of the extension tube.

Remove cannula stylet and luer lock the extension tube onto the cannula. Inject cement by turning the gray base 1/4 turn and wait one second. Repeat 1/4 turn injection and one second hesitation throughout injection. Note: 1/4 turn injection equals .1 cc of bone cement. Note: Injection and pressure may be reversed by counterclockwise turning of gray base.

PCD Kits

505-582-000
10 Gauge PCD Precision System Kit
Includes: One half dose SpinePlex bone cement, one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one 10 gauge four-faceted tip match-ground introduction needle, one 10 gauge interchangeable bevel stylet, one vacuum hose, one funnel

505-583-000
11 Gauge PCD Precision System Kit
Includes: One half dose SpinePlex bone cement
one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one 11 gauge four-faceted tip match-ground introduction needle, one 11 gauge interchangeable bevel stylet, one vacuum hose, one funnel

505-585-000
13 Gauge PCD Precision System Kit
Includes: One half dose SpinePlex bone cement
one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one 13 gauge four-faceted tip match-ground introduction needle, one 13 gauge interchangeable bevel stylet, one vacuum hose, one funnel

505-586-000
PCD Precision System with Short Extension Tube and no needles
Includes: One half dose SpinePlex bone cement, one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one short extension tube, one vacuum hose, one funnel

505-587-000
PCD Precision System Kit Without Needles
Includes: One half dose SpinePlex bone cement, one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one vacuum hose, one funnel

505-589-000
10 Gauge 9” long needle PCD Precision System Kit
Includes: One half dose SpinePlex bone cement, one precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one 10 gauge 9” long four-faceted tip match-ground introduction needle, one 10 gauge 9” long interchangeable bevel stylet, one vacuum hose, one funnel

Spineplex®
RADIOPAQUE BONE CEMENT

DESCRIPTION
Spineplex Radiopaque Bone Cement is packaged in two sterile components. One component is an ampoule of a colorless, flammable liquid monomer that has a sweet slightly acrid odor. The other component is a packet of finely divided powder.

Hydroquinone is added to prevent premature polymerization, which may occur under certain conditions; for example, exposure to light or elevated temperatures. N, N-dimethyl para toluidine is added to promote cold curing of the finished therapeutic compound.

The barium sulphate incorporated in Spineplex Radiopaque Bone Cement acts as a contrast medium for X-ray examination.

When the powder and liquid are mixed, an exothermic polymeric formation occurs resulting in a soft, pliable, dough-like mass. As the reaction progresses, a hard, cement-like complex is formed.

INDICATIONS
Spineplex Radiopaque Bone Cement is indicated for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Painful vertebral compression fractures may result from osteoporosis, benign lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).

CONTRAINDICATIONS
The use of Spineplex Radiopaque Bone Cement is contraindicated in patients with:
- Allergies or sensitivity to any of its chemical components
- Cases of active or incompletely treated infection
- Coagulation disorders, or with severe cardiopulmonary disease
- Spinal stenosis (>20% by retropulsed fragments)
- Vertebral plana (collapse >90%)
- Compromise of the vertebral body or the walls of the pedicles
- Unstable vertebral fractures due to posterior involvement
- Patient clearly improving on medical therapy
- Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture
- Non-Pathological, acute traumatic fractures of the vertebra

ADVERSE REACTIONS
Serious adverse reactions, some with fatal outcome, reported with the use of acrylic bone cement are:
- Cardiac arrest
- Myocardial infarction
- Pulmonary embolism
- Cerebrovascular accident
- Anaphylaxis
- Hypertension
- Hypotension
- Nerve entrapment

The most frequent adverse reactions reported are:
- Transitory fall in blood pressure
- Thrombophlebitis
- Hemorrhage and hematoma
- Surgical wound infection
- Deep wound infection
- Trochanteric bursitis
- Trochanteric separation

Other adverse reactions reported are:
- Heterotopic new bone
- Short term irregularities in cardiac conduction
- Pyrexia
- Hematuria
- Bladder fistula

See reverse side for complete Surgical Simplex P® information for use.

Literature Number: **9100-001-002 Rev. None**
UnDe/NAC

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crack & peel TAPE STRIP

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HALF DOSE UNIT
Each half dose packet contains 20 g of finely divided sterile powder (gamma irradiation) consisting of:
- 2.3 g Polymethyl methacrylate
- 11.7 g Methyl methacrylate-styrenecopolymer - contains Benzoyl Peroxide (1.5%)
- 6.0 g Barium Sulphate E.P.

Each half dose ampule contains 10 ml of sterile liquid (membrane filtration) consisting of:
- 9.75 ml Methyl methacrylate (monomer)
- 0.25 ml N,N-dimethyl-para-toluidine
- 0.75 mg Hydroquinone, USP

FULL DOSE UNIT
Each full dose packet contains 40 g of finely divided sterile powder (gamma irradiation) consisting of:
- 4.7 g Polymethyl methacrylate
- 23.3 g Methyl methacrylate-styrenecopolymer - contains Benzoyl Peroxide (1.5%)
- 12.0 g Barium Sulphate E.P.

Each full dose ampule contains 20ml of sterile liquid (membrane filtration) consisting of:
- 19.5 ml Methyl methacrylate (monomer)
- 0.5 ml N,N-dimethyl-para-toluidine
- 1.5 mg Hydroquinone, USP

USER/PATIENT SAFETY*
WARNINGS:
- Read and understand these instructions. Familiarization with the bone cement prior to use is important.
- For safe and efficacious use of Spineplex Radiopaque Bone Cement thesurgeon should have specific training and experience to be thoroughly familiar with the properties, handling characteristics, and application of the product.
- It is the responsibility of the surgeon performing any procedure to determine the appropriateness of this instrument and specific technique for each patient. Stryker, as a manufacturer, does not recommend surgical technique.
- Only qualified physicians, trained in percutaneous cement delivery should use this bone cement.
- Adverse patient reactions affecting the cardiovascular system have been associated with the use of bone cements. Hypotensive reactions have occurred and some have progressed to cardiac arrest. Patients should be monitored for any change in blood pressure during and immediately following the application of the bone cement. Acute hypotensive effects may be associated with the absorption of methylmethacrylate into the vascular system.
- Special precautions should be taken to detect and correct the transitory fall in blood pressure that may occur whe product is implanted into the bone.
- Methylmethacrylate has been demonstrated to cause hypersensitivity in susceptible persons, which may result in an anaphylactic response.
- The use of the product is not recommended in patients that do not exhibit a pathologic condition, such as primary or secondary osteoporosis or tumor, which would impair the ability of the patient to heal using conservative treatment methods
- Use in pregnancy: Although the results of animal teratology studies were negative, the use of the product in pregnancy or by women of childbearing potential requires that benefits be weighted against the possible hazards the mother or fetus.
- Data from clinical trials indicated the absolute necessity of strict adherence to good surgical principles and techniques. Deep wound infection is a serious postoperative complication and may require total removal of the embedded cement. Deep wound infection may be latent and not manifest itself even for several years postoperatively.
- As the liquid monomer is highly volatile and flammable, the operating room should be provided with adequate ventilation to eliminate the maximum amount of monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapors of the monomer, which may produce irritation of the respiratory tract, eyes and possibly the liver.
- The liquid component is a powerful lipid solvent. It has caused contact dermatitis in susceptible individuals. Wearing of a second pair of surgical gloves and strict adherence to the mixing instructions may diminish the possibility of hypersensitivity reactions. The compound should not be allowed to come into direct contact with sensitive tissues or to be absorbed by the body.
- Inadequate fixation or unanticipated postoperative events may affect the cement-bone interface and lead to micromotion of cement against bone surface. A fibrous tissue layer may develop between the cement and the bone. Long-term follow-up is advised for all patients on a regularly scheduled basis.
- DO NOT allow personnel wearing contact lenses to be near or involved in mixing bone cement.
- Sterile only if the package is unopened and undamaged. Single patient use only. DO NOT reuse or resterilize.
- Care should be taken in the mixing of the liquid and powder components that the entire contents of the ampoule and pouch be utilized. The mixing of the liquid monomer and the powder component should be thorough. Data from in vitro studies have shown that monomer loss is related primarily to the frequency of stirring and secondarily to the duration of stirring. Follow the instructions provided by the mixing device manufacturer. Mix the liquid and powder components for a minimum of 30 seconds and until the powder is completely saturated with the liquid.
- Caution, however, should be taken to avoid kneading of the product too long to avoid progression of the polymerization process to the point that the cement is not adequately soft and pliable to obtain good filling of the bone cavities.
- After application, during the completion of the polymerization process of the product in situ, positioning of the patient should be maintained securely to obtain proper fixation. For proper fixation, 1-2 hours or longer may be required, as determined by the patient's medical condition and the attending physician.
- The completion of polymerization occurs in the patient and is an exothermic reaction with considerable liberation of heat. Temperatures occurring during the polymerization have been reported as high as 110° Centigrade. The long-term effect of the heat produced along with the resulting tissue damage is not known.

***If you have questions, call your Stryker representative or Stryker Customer Service at 1-800-253-3210. Outside the USA, contact your nearest Stryker subsidiary.**

USER/PATIENT SAFETY* (cont.)
WARNINGS:
- Use appropriate imaging techniques to verify correct needle placement, absence of damage to surrounding structures, and appropriate location of the injected bone cement. Use imaging, such as fluoroscopy, to assess the ability of the vertebra to contain the injected bone cement.
- Injecting too much cement or injecting the cement too quickly may result in cement leakage. Cement leakage may cause tissue damage, and nerve or circulatory problems.
- Leaks can also occur when injecting if the needle is in a vein or if unseen microfractures are prevalent.
- If bone cement is seen outside of the vertebral body or in the circulatory system during percutaneous vertebroplasty or kyphoplasty, immediatelystop the injection.
- The long-term effects of the bone cement in the spine have not been established.

ADVERSE REACTIONS
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- Cardiac arrest
- Myocardial infarction
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Other adverse reactions reported are:
- Heterotopic new bone
- Short term irregularities in cardiac conduction
- Pyrexia
- Hematuria
- Bladder fistula

IMPORTANT PHYSICIAN INFORMATION
- Adverse reactions affecting the cardiovascular system have been attributed to leakage of unpolymerized liquid monomer into the circulatory system. More recent data indicate that the monomer undergoes rapid hydrolysis to methacrylic acid, and that a significant fraction of the circulating methacrylate is in the form of the free acid rather than the methyl ester. Correlation between changes in circulating concentrations of methyl methacrylate/methacrylic acid and changes in blood pressure has not been established.
- Hypotensive episodes reported appear to occur primarily in patients with elevated or high normal blood pressure, in hypovolemia, and in individuals with pre-existing cardiovascular abnormalities. If a hypotensive reaction occurs, the onset may appear 10 to 165 seconds following application of the bone cement. Its duration may last from 30 seconds to 5-6 minutes.

RECOMMENDED MATERIAL AND EQUIPMENT
Cement Media
- Stryker Spineplex Radiopaque Bone Cement (Full or Half Dose Unit)
- One (1) Full Dose of cement. Each dose provides 40 grams of powder and 20 ml of liquid. Cement is sold without the mixing system.
- One (1) Half Dose of cement. Each dose provides 20 grams of powder and 10 ml of liquid. Cement is sold without the mixing system.
- Refer to System Selection Based on Dosage for part numbers where the cement is sold packaged as a kit with the mixing system. Vacuum Source The Stryker ACM PCD System and Stryker PCD Precision System require a vacuum source:
- Stryker Manual High Vacuum Pump (REF 206), or
- Stryker Automatic High Vacuum Foot Pump (REF 206-500)

Imaging Technology
- C-Arm Fluoroscope (good quality verified to provide adequate visualization of cement)

Dosage
As required for adequate fixation of the pathological fracture.

SYSTEM SELECTION BASED ON DOSAGE
When used, the powder and liquid components are mixed together and applied using a bone cement delivery system designed for percutaneous cement delivery treatment.
The Stryker ACM PCD System and the PCD Precision System are intended for mixing bone cement and delivering it percutaneously. The mixing system must accommodate the required bone cement dosage. See System Selection Based on Dosage Table to determine which mixing system to use. REF 306-650.

SYSTEM SELECTION* BASED ON DOSAGE TABLE

If using a full dose unit (40 grams) of Spineplex, use one of these
Stryker ACM PCD Systems:**
0405-583-000 (with 11 gauge needle)
0405-584-000 (with Luer lock nozzle)
0405-585-000 (with 13 gauge needle)
0405-586-000 (without needles)

If using a half dose unit (20 grams) of Spineplex, use one of these
Stryker PCD Precision Systems:
0505-582-000 (with 10 gauge needle)
0505-583-000 (with 11 gauge needle)
0505-585-000 (with 13 gauge needle)
0505-586-000 (with short tube)
0505-587-000 (without needles)
0505-589-000 (with 10 gauge, 9 in. long needle)

* NOTE: All part numbers listed in this table, both 405 and 505 series, are sold with Spineplex.
** NOTE: The Stryker ACM PCD Systems require a Stryker Percutaneous Cement Gun

PREPARATION AND ADMINISTRATION

WARNING: If any packaging is damaged, DO NOT use this product. The liquid monomer, the ampoule and the ampoule package have been pre-sterilized.
1. To mix, empty the entire contents of the packet containing the powder component into an appropriate sterile, inert mixing device.
2. Add the entire contents of the ampoule containing the liquid component to the powder component. DO NOT add the powder to the liquid.
3. Mix with a suitable inert device, following the device manufacturer's instructions, for a minimum of 30 seconds and until the powder is completely saturated with the liquid.

CAUTIONS:
- DO NOT apply the cement until two minutes after adding the liquid component to the powder component, and the cement does not stick to the surgical gloves of the operator.
- The correct working consistency of the product for application to bone is best determined by the experience of the surgeon.

4. Select an appropriate method to apply the cement to bone. If applicable, follow the device manufacturer's instructions.

SAFE DISPOSAL
- Allow mixed cement to set before disposal with other clinical waste.
- To dispose of the liquid or powder separately, contact your local disposal authority.

STORAGE
WARNING: Flammable;
Keep away from sources of ignition.
- Store in a dark, dry place below 77°F [25°C].
- DO NOT use this product after its expiry date.

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