**Interventional Pain**

**PCD Kits**

505-582-000
10 Gauge PCD Precision System Kit

- **Includes:**
  - One 11 gauge precision mixer/delivery system, one vacuum hose, one funnel, 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.

505-583-000
11 Gauge PCD Precision System Kit

- **Includes:**
  - One 11 gauge precision mixer/delivery system, one vacuum hose, one funnel, 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.

505-586-000
PCD Precision System Kit 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 endocarditis cement tube, one delivery cartridge.

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 endocarditis cement tube, one delivery cartridge.

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 endocarditis cement tube, one delivery cartridge.

**Spineplex® Radiopaque Bone Cement**

**DESCRIPTION**

Spineplex Radiopaque Bone Cement is a polymeric bone cement consisting of an inorganic polymeric base and a liquid monomer. After mixing, a hard, cement-like complex is formed.

**INDICATIONS**

- **Use for:**
  - Painful vertebral compression fractures may result from osteoporosis, benign lesions or acute fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

**CONTRAINdications**

- **Use of Spineplex Radiopaque Bone Cement is contraindicated in patients with:**
  - Serious bleeding, coagulation disorders, or with severe cardiopulmonary disease

**ADVERSE REACTIONS**

- **Myocardial infarction**
- **Cardiac arrest**
- **Prophylaxis in metastatic or osteoporotic patients with no evidence of acute fracture**
- **Vertebral plana (collapse >90%)**
- **Spinal stenosis (>20% by retropulsed fragments)**
- **Coagulation disorders, or with severe cardiopulmonary disease**

Other adverse reactions reported are:

- **Hematoma or hematocele**
- **Dural tear**
- **Spinal nerve compression**
- **Arachnoiditis**
- **Spinal cord compression**
- **Deep wound infection**
- **Surgical wound infection**

The most frequent adverse reactions reported are:

- **Transitory fall in blood pressure**
- **Transitory increase in blood pressure**
- **Transient headache**
- **Other adverse reactions reported are:**
- **Short-term irritability in cardiac conduction**
- **Fainting**
- **Hiccups**
- **Rales/Effusions**

**NOTICE**

- **See reverse side for complete Surgical Simplex® 5 Information for use.**
**WARNING:**

**USER/PATIENT SAFETY**

- It is recommended that the operator wear a mask during the procedure to prevent inhalation exposure to the monomer vapor. Caution should be exercised during the mixing of the two components to prevent excessive exposure to the concentrated vapor of the monomer, which may produce irritation of the respiratory tract, eyes and skin.\[1\]

**CONTRAINDICATIONS**

- Painful vertebral compression fractures may result from osteoporosis, benign fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Spineplex Radiopaque Bone Cement is indicated for the fixation of pathological lesions (hemangioma), and malignant lesions (metastatic cancers, myeloma).\[2\]

**ADVERSE REACTIONS**

- Pulmonary embolism
- Cardiac arrest
- Transitory fall in blood pressure
- Hypotensive episodes reported appear to occur primarily in patients with elevated or high normal blood pressure that may occur when product is implanted into the bone.\[3\]

**SAFE DISPOSAL**

- To dispose of the liquid or powder separately, contact your local disposal authority.

**SYSTEM SELECTION BASED ON DOSAGE**

- When using a half dose unit (20 grams) of Spineplex, use one of these: 0405-584-000 (with Luer lock nozzle) 0405-585-000 (with 13 gauge needle)
- When using a full dose unit (40 grams) of Spineplex, use one of these: 0505-585-000 (with 13 gauge needle) 0505-586-000 (without needles)

**ADMINISTRATION**

- The operator should be aware of the potential hazards of the monomer and should have available the necessary equipment to counteract any systemic effects should any exposure occur.\[3\]

**STORAGE**

- Store in a dark, dry place below 77°F [25°C]. Do not allow the product to become wet.\[3\]

**REFERENCES**