

Stryker Interventional Pain

A Complete Solution for
Vertebral Compression Fractures



**Products designed to meet the specific needs
of percutaneous cement injection procedures.**

Stryker Bone Cements

As one of the world's leading manufacturers of bone cement, Stryker has implanted more than 23 million doses over the last three and a half decades. This success is grounded in Simplex™ P bone cement, the first surgical bone cement approved by the FDA for total hip replacement. Since then, Stryker has continued to set an industry standard in providing physicians with a range of bone repair cements that address viscosity and working time preferences for percutaneous vertebroplasty.

1958

Simplex C cement introduced in Europe

1962

Simplex P bone cement introduced in Europe

1971

Simplex P first to receive FDA approval in the U.S. for total hip arthroplasty

1973

Simplex P bone cement approved for total knee arthroplasty

1975

Simplex antibiotic bone cement (with Erythromycin and Collistin) introduced in Europe

1976

Simplex P approved for pathological fractures and general prosthetic fixation



VertaPlex™

Overview

VertaPlex™ has been developed for the physician desiring higher initial viscosity and longer working time. Great for kyphoplasty and multiple level vertebroplasties, VertaPlex™ maintains a desirable toothpaste-like consistency for an average of 18 minutes.

Features

- Higher initial viscosity
- Increased working time – approximately 18 minutes
- In vivo (37°C) set time 10.2 minutes
- Lower creep rate
- Greater visibility in radiology images
- 30% barium sulfate concentration

Recommended Companion Products

- Xvoid
- AutoPlex
- VertePort
- All Vertebroplasty Needles

VertaPlex Ordering Information (Sterile; 2 per box)

406-422-000

VertaPlex 20 Gram Twin Pack (1/2 Dose)

1999	2000	2003	2003	2004	2004-07	2008
Over 15 million doses of Simplex P have been implanted	Simplex P with tobramycin introduced in Europe	Simplex P with tobramycin introduced in U.S.	SpinePlex introduced in Europe	SpinePlex introduced in U.S.	SpinePlex used in thousands of vertebral compression fractures worldwide	VertaPlex introduced worldwide

SpinePlex™

Overview

SpinePlex™ is a derivative of Simplex P bone cement. It contains the same polymethyl metacrylate and is manufactured using the same proprietary process. Simplex P has proven through clinical testing to have high fatigue,⁴ compressive,⁵ and flexural strengths,⁵ and low creep.⁶

Features

- Derivative of Simplex P bone cement
- Proven strength⁷
- Optimal viscosity is attained quickly
- Working time of 10-12 minutes
- In vivo (37°C) set time 8.2 minutes
- Greater visibility in radiology images
- 30% barium sulfate concentration



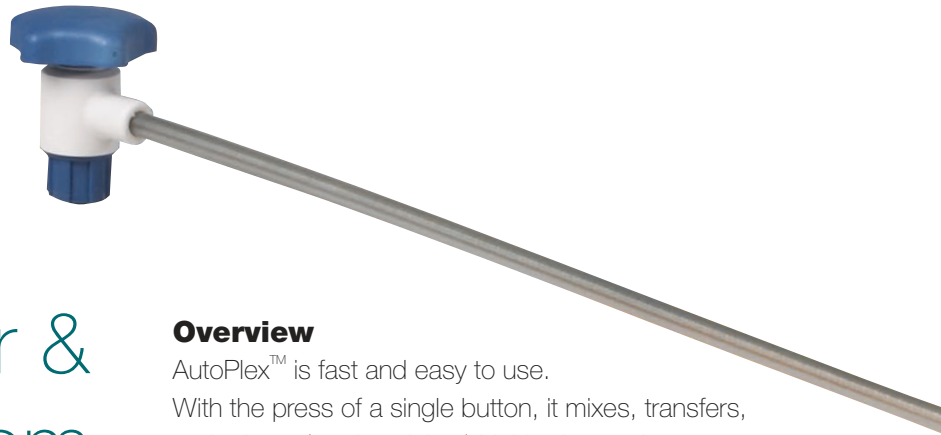
Recommended Companion Products

- PCD
- VertePort
- All Vertebroplasty Needles

SpinePlex Ordering Information

(Sterile; 2 per box)

406-222-000
SpinePlex 20 Gram Twin Pack (1/2 Dose)



AutoPlex™ Mixer & Delivery System

Overview

AutoPlex™ is fast and easy to use.

With the press of a single button, it mixes, transfers, and primes (ready to inject) highly viscous bone cement for delivery in less than 60 seconds.

Mixing

- Automatically mixes, transfers, primes, and is ready for delivery in less than 60 seconds, streamlining procedure time
- Automatic blending and transferring of cement
- Provides consistent and thorough mixing, eliminating human error and variability

Unique to Stryker*

Delivery

- Lightweight, comfortable, ergonomic, handheld delivery injector
- 14cc of deliverable cement
- Closed mixing, transfer, and delivery system prevents exposure to harmful fumes
- 40cm flexible extension tube provides radiation safety
- New ergonomic luer design
- Delivers 0.25cc per half turn
- Simple and reliable handheld injection

Unique to Stryker*

Step 1



Add powder through supplied funnel

Step 2



Add monomer

Step 3



Lock lid onto mixing chamber

Step 4



Press and release mixing button

AutoPlex Ordering Information

(Sterile; 2 per box)

605-887-000

AutoPlex System Kit without Needles



Step 5



**Remove tube from
mixing device**

Step 6



**Remove delivery device
from mixing device**

Recommended Companion Products

- Xvoid
- VertaPlex (1/2 Dose)
- VertePort
- All Vertebroplasty Needles

PCD™ : Precision Cement Delivery

Overview

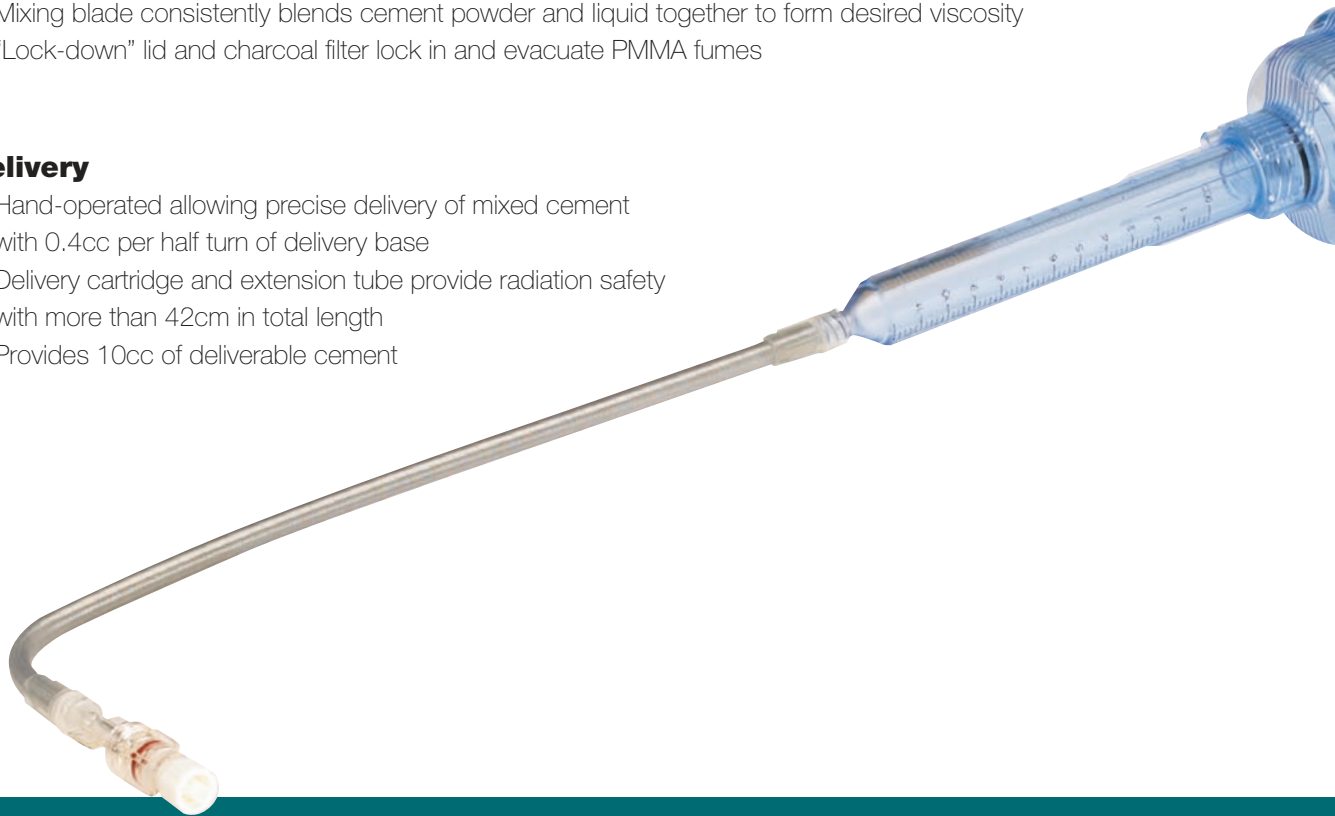
An all-in-one mix and delivery system, PCD offers physicians ease of use, desired cement consistency, and procedure efficiency.

Mixing

- Mixes in approximately 2 minutes
- Closed vacuum mixing system is proven to enhance the cement's capabilities
- Hands-free transfer of mixed cement to delivery cartridge
- Mixing blade consistently blends cement powder and liquid together to form desired viscosity
- "Lock-down" lid and charcoal filter lock in and evacuate PMMA fumes

Delivery

- Hand-operated allowing precise delivery of mixed cement with 0.4cc per half turn of delivery base
- Delivery cartridge and extension tube provide radiation safety with more than 42cm in total length
- Provides 10cc of deliverable cement



Step 1



Add powder and monomer through supplied funnel

Step 2



Attach mixing blade and lock into place

Step 3



Mix cement

Step 4



Remove hand mixer: Push grey button inward, rotate clockwise, then pull handle straight up and out of mix chamber



PCD Kits Ordering Information

(Sterile; 4 per box)

506-482-000

10 Gauge PCD Precision System Kit

Includes: 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.

506-483-000

11 Gauge PCD Precision System Kit

Includes: 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.

506-485-000

13 Gauge PCD Precision System Kit

Includes: 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.

506-486-000

PCD Precision System Kit Without Needles

Includes: One precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one vacuum hose, one funnel.

506-489-000

10 Gauge 9" long needle PCD

Precision System Kit

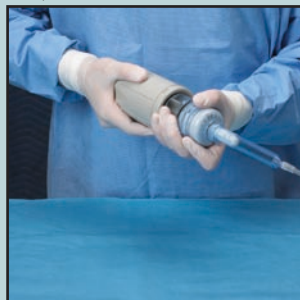
Includes: One precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one 10 gauge 9" long four-faceted tip match-ground introduction needle, one 10 gauge 9" long interchangeable bevel stylet, one vacuum hose, one funnel.

Step 5



Attach extension tube by rotating counterclockwise

Step 6



Transfer and prime system by turning the base of the mixing chamber clockwise

Recommended Companion Products

- SpinePlex (1/2 Dose)
- VertePort
- All Vertebroplasty Needles

Vertebral Bone Biopsy Kit

Overview

The Stryker Vertebral Bone Biopsy Kit can be used with our standard 10, 11, and 13 gauge 5" needles. The coaxial design allows for biopsy collection of a core sample while advancing the access needle into the vertebral body. This streamline technique can be used in conjunction with a vertebroplasty procedure or independent biopsy.

Features

- Pre-packaged in 10, 11, and 13 gauges
- Easy, streamlined approach
- Enables access for subsequent procedures
- Radiolucent handles allow unobstructed image of bony landmarks and precise needle placement



Bone Biopsy Kit Ordering Information (Sterile; 6 per box)

306-105-000

10 Gauge 5" Bone Biopsy Kit

306-195-000

10 Gauge 9" Bone Biopsy Kit

306-115-000

11 Gauge 5" Bone Biopsy Kit

306-135-000

13 Gauge 5" Bone Biopsy Kit

Recommended Companion Products

- 10 Gauge 5" Diamond Tip Match-Ground Introduction Needles
- 11 Gauge 5" Diamond Tip Match-Ground Introduction Needles
- 13 Gauge 5" Diamond Tip Match-Ground Introduction Needles

Needles Ordering Information

(Sterile; 6 per box)

306-100-000

10 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-101-000

10 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-190-000

10 Gauge 9" Diamond Tip Match-Ground Introduction Needle

306-191-000

10 Gauge 9" Bevel Tip Match-Ground Introduction Needle

306-114-000

11 Gauge 4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

306-110-000

11 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-111-000

11 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-134-000

13 Gauge 4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

306-130-000

13 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-131-000

13 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-144-000

14 Gauge 4.4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

Recommended Companion Products

- PCD
- VertaPlex
- SpinePlex (1/2 Dose)

Needles

Overview

Stryker's needles offer flexibility in accessing the vertebral body and delivering bone cement during VCF treatments. The easy to use match-ground diamond tips are sharp and efficient in cutting bone, while the beveled stylets offer high control and maneuverability.

Features

- Four-faceted needle cannula is ground down to match stylet, reducing tissue 'catching' when introduced
- Diamond and bevel-tipped stylets are interchangeable with cannulae
- Bevel markings
- Color-coded stylets for easy identification
- 10, 11, 13 gauges, 5" length
- 10 gauge, 9" length
- 11 and 13 gauge, 4" length
- 14 gauge, 4.4" length
- Radiolucent handles provide clear visibility under fluoroscopy



VertePort™

Overview

VertePort is a coaxial, hollow-needle access and delivery system developed specifically for vertebral augmentation. The system offers multiple ways to deliver bone cement during VCF treatments.

By providing continuous access to the vertebral body, VertePort increases control while delivering cement with the use of a traditional injector.

If used to hand obturate cement delivery, VertePort's mechanical advantage allows for delivery of thicker cement and increased working time compared to traditional injectors and syringes.



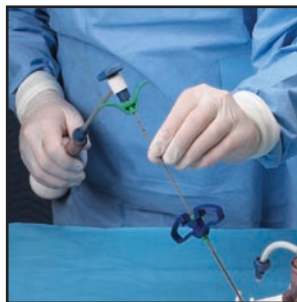
Features

- 10 gauges - 0.8cc
- 11 gauges - 0.5cc
- Maximizes flexibility during VCF treatment
- Provides constant unobstructed access to the vertebral body
- Allows easy delivery of high-viscosity cement
- Precise control
- Ability to deliver cement through hand obturation and / or injector
- Excellent tactile feel
- Extend cement working time with use of hand obturation

Step 1

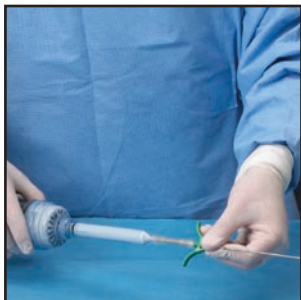


Step 2

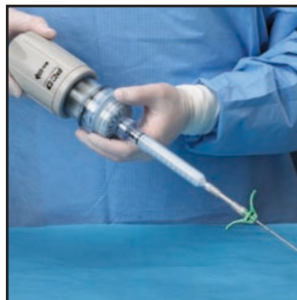


Filling of cement cannula using AutoPlex

Step 1

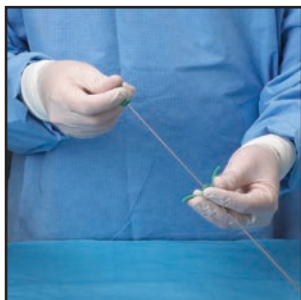


Step 2



Filling of cement cannula using PCD

Step 1



Step 2



Hand obturation

VertePort Ordering Information

Access Cannulae

(Sterile; 6 per box)

306-400-000

10 Gauge 5.75" Long Stylet Access Cannula

306-430-000

10 Gauge 5" Short Stylet Access Cannula

306-110-000

11 Gauge 5" Short Stylet Access Cannula

Cement Cannulae

(Sterile; 18 per box)

306-510-000

11 Gauge Cement Cannula
(for use with 11 gauge 5" access needle
306-110-000)

306-410-000

10 Gauge Cement Cannula
(for use with 10 gauge long and short access
needles 306-400-000 and 306-430-000)

Recommended Companion Products

- AutoPlex
- PCD
- VertaPlex (1/2 Dose)
- SpinePlex (1/2 Dose)

AutoPlex Kits

(Sterile; 2 per box)

605-887-000

AutoPlex System Kit without Needles

VertaPlex Cement

(Sterile; 2 per box)

406-422-000

VertaPlex 20 Gram Twin Pack (1/2 Dose)

SpinePlex Cement

(Sterile; 2 per box)

406-222

SpinePlex 20 Gram Twin Pack (1/2 Dose)

VertePort Access Cannulae

(Sterile; 6 per box)

306-400-000

10 Gauge 5.75" Long Stylet Access Cannula

306-430-000

10 Gauge 5" Short Stylet Access Cannula

306-110-000

11 Gauge 5" Short Stylet Access Cannula

VertePort Cement Cannulae

(Sterile; 18 per box)

306-510-000

11 Gauge Cement Cannula (for use with
11 gauge 5" access needle 306-110-000)

306-410-000

10 Gauge Cement Cannula (for use with
10 gauge long and short access needles 306-
400-000 and 306-430-000)

PCD Kits

(Sterile; 4 per box)

506-482-000

10 Gauge PCD Precision System Kit

Includes: 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.

506-483-000

11 Gauge PCD Precision System Kit

Includes: 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.

506-485-000

13 Gauge PCD Precision System Kit

Includes: 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.

506-486-000

PCD Precision System Kit Without Needles

Includes: One precision mixer/delivery system, one mixing head assembly, one delivery cartridge, one right angle extension tube, one vacuum hose, one funnel.

506-489-000

10 Gauge 9" long needle PCD Precision System Kit

Includes: 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.

Bone Biopsy Kits

(Sterile; 6 per box)

306-105-000

10 Gauge 5" Bone Biopsy Kit

306-195-000

10 Gauge 9" Bone Biopsy Kit

306-115-000

11 Gauge 5" Bone Biopsy Kit

306-135-000

13 Gauge 5" Bone Biopsy Kit

Needles

(Sterile; 6 per box)

306-100-000

10 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-101-000

10 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-190-000

10 Gauge 9" Diamond Tip Match-Ground Introduction Needle

306-191-000

10 Gauge 9" Bevel Tip Match-Ground Introduction Needle

306-114-000

11 Gauge 4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

306-110-000

11 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-111-000

11 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-134-000

13 Gauge 4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

306-130-000

13 Gauge 5" Diamond Tip Match-Ground Introduction Needle

306-131-000

13 Gauge 5" Bevel Tip Match-Ground Introduction Needle

306-144-000

14 Gauge 4.4" Diamond Tip Match-Ground Introduction Needle and Bevel Stylet

Notes

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Joint Replacements

Trauma, Extremities & Deformities

Craniomaxillofacial

Spine

Biologics

Surgical Products

Neuro & ENT

Interventional Pain

Navigation

Endoscopy

Communications

Imaging

Patient Handling Equipment

EMS Equipment

Footnotes

1. A comprehensive classification of thoracic and lumbar injuries, F. Magerl, Eur Spine J (1994) 184-201
2. An In Vivo Comparison of the Potential for Extravertebral Cement Leak After Vertebroplasty and Kyphoplasty, Frank M. Phillips, Spine Volume 27 (2002) 2173-2179
3. Vertebroplasty and Kyphoplasty: A Systematic Review of 69 Clinical Studies, Paul A. Hulme, Spine Volume 31 (2006) 1983-2001
4. Davies JB, Jasty M, O'Connor DO, Burke DW, Harrigan TP, Harris WH. The effect of centrifuging bone cement. J Bone Joint Surg Br 1989; 71(1):39-42
5. Hansen D, Jensen JS. Mixing does not improve mechanical properties of all bone cements. Acta Orthop Scand 1992; 63(1): 13-18
6. Holm NJ. The relaxation of some acrylic bone cements. Acta Orthop Scand 1980; 51(5): 727-31
7. Grados, F. et al. Long-term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. Rheumatology 2000;39:1410-1414

* Information current as of 13.12.07

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