stryker

Your single source for **VCF solutions**

Every VCF is unique.

Now you have more treatment options .

Osteoporotic fractures are a serious and growing problem for older adults and the healthcare system. In fact, one in two women and one in four men over the age of 50 will have an osteoporotic fracture during their lifetime.[1] Vertebral compression fractures (VCFs) are the most common with an estimated 700,000 such fractures reported each year in the US.[2]

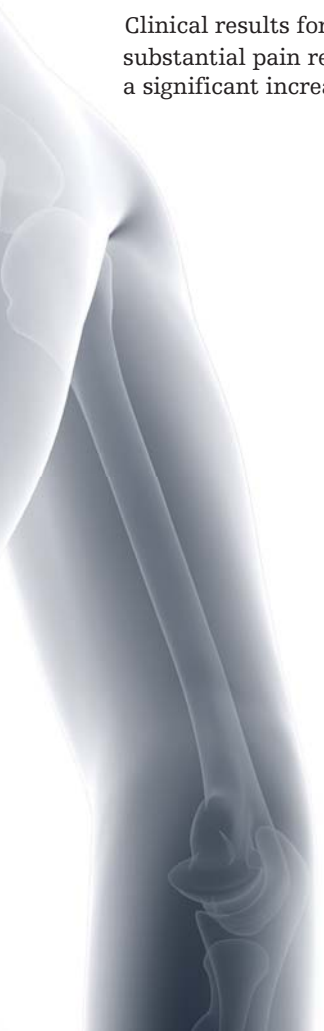
Relieving pain, improving lives.

With the addition of the AVAflex Balloon System, we offer you a broad portfolio of products for VCF treatments. From our iVAS Balloon System to our mixer and delivery systems, implants and needles, our portfolio of products lets you customize your treatment approach.

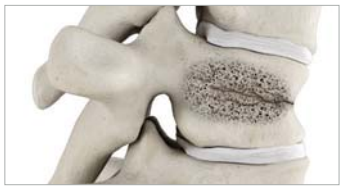
Vertebroplasty involves injection of bone cement or bioactive resin directly into a fractured vertebral body from a percutaneous approach. The hardened cement or bioactive resin stabilizes the fracture, relieving pain.[3,4]

Vertebral augmentation is a treatment option for vertebral compression fractures that creates a void in the cancellous bone. This procedure helps ensure controlled and contained cement delivery into the fractured vertebral body.

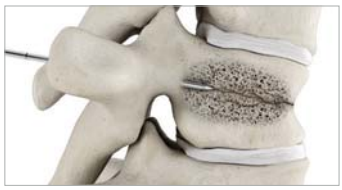
Clinical results for both procedures show substantial pain relief [5,6] and potentially a significant increase in quality of life [7,8].



Vertebroplasty

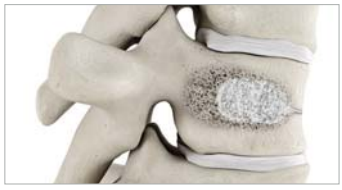


Vertebral compression fracture is identified



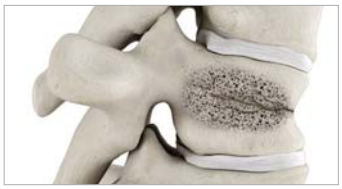
Needle is guided into fractured vertebra using fluoroscopy

Bone cement or bioactive resin is injected

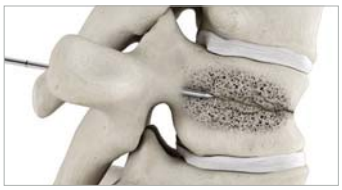


Stabilized vertebral body

Vertebral augmentation

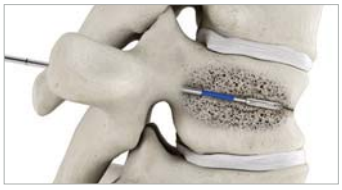


Vertebral compression fracture is identified

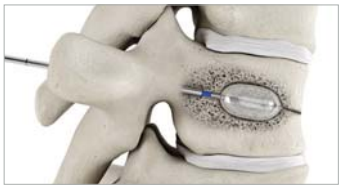


Needle is guided into fractured vertebra using fluoroscopy

Hand drill is inserted into the anterior third of the vertebral body to create a pathway

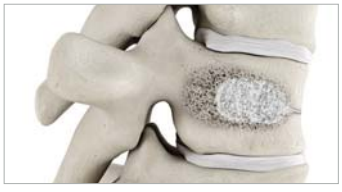


Balloon catheter is inserted into the fractured vertebra



The balloon is inflated, compacting the trabeculae and creating a cavity

Once the balloon is deflated and withdrawn, the cavity is filled with bone cement or bioactive resin



Stabilized vertebral body

Vertebral augmentation

We provide you with multiple options for treating VCFs based on fracture anatomy and presentation.

Cements

From bioactive resins to PMMA cements, we continue to supply a large choice of bone cements.

Mixer and delivery systems

We offer a range of bone cement mixing and delivery systems that are designed to provide physicians increased control and improve ease of use while treating VCFs.

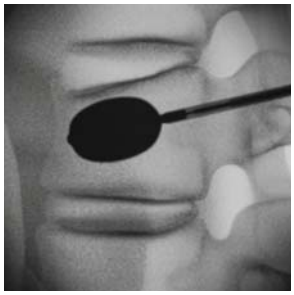
Bone biopsy and needles

We offer access flexibility in the vertebral body through the coaxial design of biopsy needles that allow for collection of a core sample during the procedure.

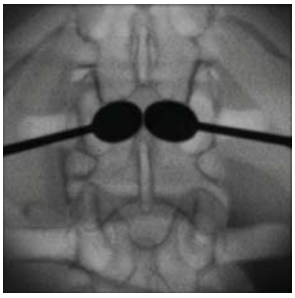
Vertebral augmentation

iVAS
Balloon System

Our iVAS Balloon System, used during vertebral augmentation, utilizes a balloon catheter to create a void in the collapsed vertebra, helping to allow for controlled and contained cement delivery. Hardened cement creates an internal cast that stabilizes the fracture, thereby alleviating pain of patients.[6]



Unipedicular vertebral augmentation



Bipedicular vertebral augmentation

Features

Balloon catheter

- Stiff distal balloon catheter provides rigidity for smooth insertion.
- Flexible proximal catheter allows for easy maneuverability.
- The radiopaque markers on the balloon catheter help facilitate accurate visualization and placement of the balloon.

Access cannula/stylet

- The hand drill cuts cleanly through cancellous bone to create a channel for balloon placement.
- Graduation markings on the access cannula assist in measuring needle depth.
- Available in 11g, 10g, and 8g.

Hand tool options

- Biopsy tools are available to extract core sample from cancellous bone
- Drill

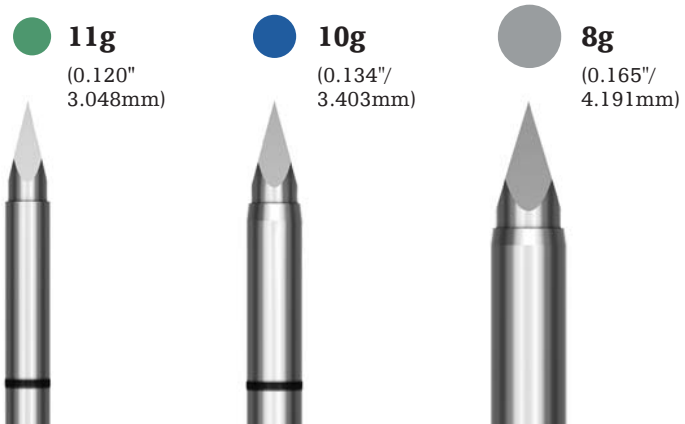
11g iVAS System

The 11g access cannula has a cross-sectional area that is 47% smaller than an 8g access cannula and 20% smaller than a 10g access cannula.

Features

- Helps reduce footprint and trauma*
- Designed for easier access and navigation inside pedicle*
- Supports the ability to perform vertebral augmentation/ kyphoplasty at high(er) levels of of the spine*
- Helps decrease opportunity for canal breach*

*As compared to larger gauge sizes



Ordering information

iVAS Kits

Each kit includes: access cannula with diamond tip stylet, bevel tip stylet, balloon catheter, inflator, syringe

0705-310-000
11g 10mm iVAS Kit (3 per box)

0705-315-000
11g 15mm iVAS Kit (3 per box)

0705-110-000
10g 10mm iVAS Kit (3 per box)

0705-115-000
10g 15mm iVAS Kit (3 per box)

0705-120-000
10g 20mm iVAS Kit (3 per box)

0705-815-000
8g 15mm iVAS Kit (3 per box)

0705-820-000
8g 20mm iVAS Kit (3 per box)

À la carte

0705-310-500
11g 10mm iVAS Balloon (3 per box)

0705-315-500
11g 15mm iVAS Balloon (3 per box)

0705-110-500
10g 10mm iVAS Balloon (3 per box)

0705-115-500
10g 15mm iVAS Balloon (3 per box)

0705-120-500
10g 20mm iVAS Balloon (3 per box)

Supplemental products

0306-116-000
11g iVAS Bone Biopsy Kit
(6 per box)

0306-811-000
11g iVAS Hand Drill (6 per box)

0306-330-000
11g iVAS Access Cannula (6 per box)

0306-511-000
11g VertePort Cement Cannula
(18 per box)

0306-104-000
10g iVAS Bone Biopsy Kit
(6 per box)

0306-810-000
10g iVAS Hand Drill (6 per box)

0306-530-000
10g iVAS Access Cannula (6 per box)

0306-410-000
10g VertePort Cement Cannula
(18 per box)

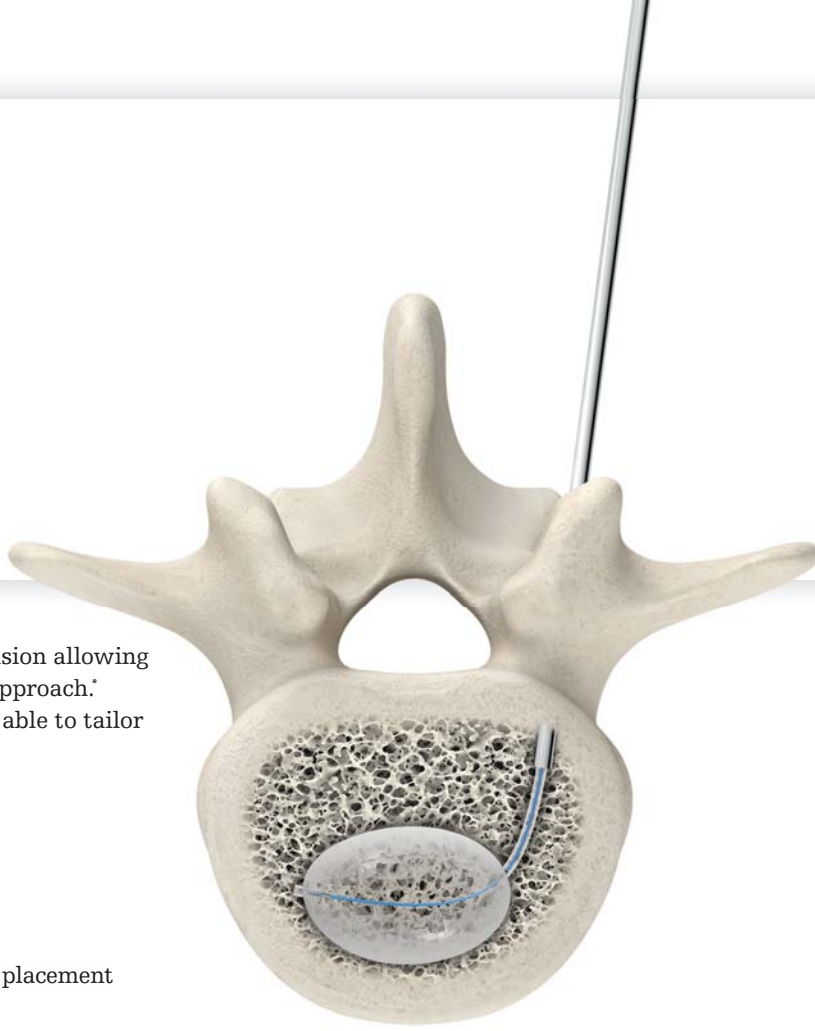
0306-080-000
8g iVAS Access Cannula
(6 per box)

0306-125-000
8g iVAS Bone Biopsy Kit
(6 per box)

0306-808-000
8g iVAS Hand Drill (6 per box)

0306-310-000
8g VertePort Cement Cannula
(18 per box)

AVAflex
Balloon System

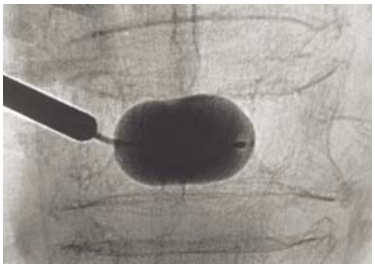


The AVAflex Balloon System combines confidence and precision allowing bipedicular results to be achieved through a unipedicular approach.* With our multiple balloon sizes and needle gauges, you are able to tailor your treatment to your preferences and patient needs.

Features

- Less invasive offering**
- Helps reduce footprint and trauma**
- Curved peek sheath introducer allows for targeted balloon placement
- Directional markings to identify direction of curve
- Targeted cement delivery
- Depth markings to accurately place 15, 20, and 30mm balloons
- Available in 10g and 11g

* Based on fill volume
** As compared to larger gauge sizes



Fluoroscopy of a void created by the AVAflex System

11g AVAflex System kit

10g AVAflex System kit

13g iVAS
Balloon System

13g iVAS Balloon System

The 13g access cannula has a cross-sectional area that is 37% smaller than an 11g access cannula, 50% smaller than a 10g access cannula, and 67% smaller than an 8g access cannula.

Features

- The smallest diameter balloon kit on the market*†
- Helps reduce footprint and trauma*
- Designed for easier access and navigation inside pedicle*
- Supports the ability to perform vertebral augmentation/ kyphoplasty at higher levels of the spine *
- Helps decrease opportunity for canal breach*

*As compared to larger gauge sizes
†As of September 2018

13g iVAS System kit

Ordering information

AVAflex Kits

11g kit includes: access cannula with diamond tip stylet, bevel tip stylet, curved introducer loaded with peek sheath, balloon catheter, curved needle, cement introducer with touhy borst, inflator, syringe

1031-115-000
11g 15mm vertebral balloon system Kit (1 per box)

1031-120-000
11g 20mm vertebral balloon system Kit (1 per box)

1031-130-000
11g 30mm vertebral balloon system Kit (1 per box)

10g kit includes: access cannula with diamond tip stylet, bevel tip stylet, curved needle loaded with peek sheath, balloon catheter, cement introducer with touhy borst, inflator, syringe

1031-015-000
10g 15mm vertebral balloon system Kit (1 per box)

1031-020-000
10g 20mm vertebral balloon system Kit (1 per box)

1031-030-000
10g 30mm vertebral balloon system Kit (1 per box)

13g iVAS Balloon System

13g kit includes: access cannula with diamond tip stylet, bevel tip stylet, balloon catheter, cement introducer with touhy borst, inflator, syringe

1021-310-000
13g 10mm iVas Single Kit (1 per box)

1021-315-000
13g 15mm iVas Single Kit (1 per box)

1021-320-000
13g 20mm iVas Single Kit (1 per box)

Curette

The Curette is intended for displacing cancellous bone to use during percutaneous balloon assisted vertebral augmentation.

Features

1 **Raised thumbwheel allows for** precise depth adjustment for preferred bone displacement

2 **Depth markings** at every 2mm help to ensure the accurate identification of device depth

3 **Wide-grip ergonomic handle** with integrated thumbwheel for single-handed device control

4 **Nitinol distal tip** geometry for bone displacement

Specifications

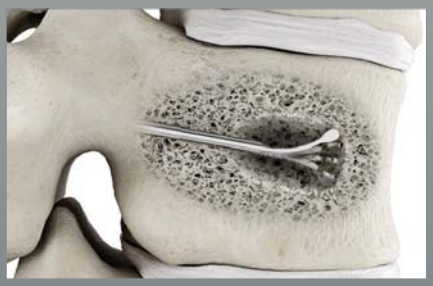
Ordering information

0306-621-000
11g Curette
(1 per box)

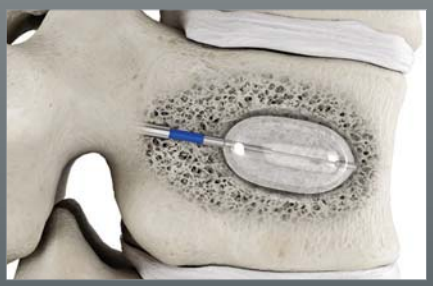
0306-620-000
10g Curette
(1 per box)

Procedure overview

No balloon inflation due to hard or sclerotic bone



Insertion of Curette to displace bone



Re-insertion of balloon properly inflated

Cements

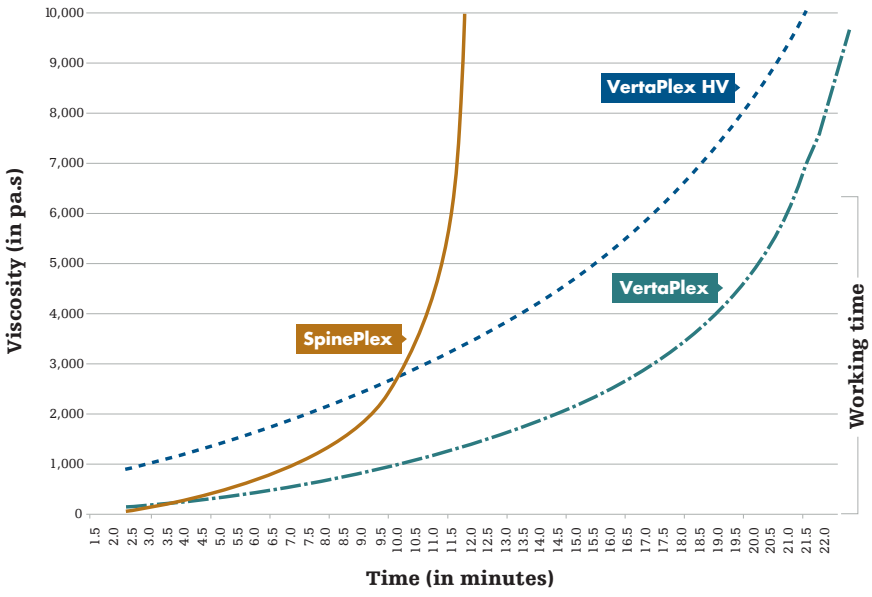
Vertebral compression fractures (VCFs) and **cement choices**

When treating VCFs with vertebral augmentation or vertebroplasty, it's the cement, the part of the procedure that remains with the patient, that makes the lasting impression. We are dedicated to providing you with a large variety of bone cements as well as a large array of tools to help your patients return to active living.

PMMA bone cements

- Three different treatment options:
  - **VertaPlex HV Bone Cement** has high initial viscosity with extended working time
  - **VertaPlex Bone Cement** has low to medium initial viscosity with maximum working time
  - **SpinePlex Bone Cement** has low to medium initial viscosity with shorter working time
- Variety of viscosity and set-time properties allow physicians to tailor to patients' procedural needs

Bone cement viscosity comparison[9]



Cortoss Bone Augmentation Material

See page 15 for ordering information.

PMMA bone cements

See page 14 for ordering information.

Cortoss Bone Augmentation Material

- Bioactive resin that creates an environment conducive for bone growth[10]
- Hydrophilic resin "seeks out" and stabilizes micro fractures[11]
- Restores loading patterns similar to undamaged vertebrae within vertebral body[12]
- "Snap set" results in immediate weight bearing (72% of compressive strength in 15 minutes)[13]
- Improved pain relief and function[14]
- Trend toward less adjacent level fractures[14]

Mechanical properties of bone cements

Property	Clinical relevance	Human bone[15-18]	Cortoss Material[12,13,19-21]	PMMA[12,13,19-21]
Static compressive strength (MPa)	How much weight and compression it can take	167–215	200–220	54–103
Compressive modulus (GPa)		14.7–19.7	8.2	3.5
Static tensile strength (MPa)	How much force it takes to pull it apart	70–140	52–62	24–48
Tensile modulus (GPa)		10.9–14.8	8–12	2–4
Compressive creep strain (50 MPa 24 hr)	How it withstands repetitive stress		0.5–2.2%	20–27%
Compressive endurance (50 MPa)			5–10 million cycles	2,500–100,000 million cycles

VertaPlex HV
Bone Cement

VertaPlex HV Bone Cement is a high viscosity cement that contributes to a controlled interdigitation and fill. VertaPlex HV Cement reaches a thick viscosity as soon as it's mixed and maintains viscosity for an average of 18 minutes,[9] giving physicians a long working time.

In 2008 we released VertaPlex Cement, addressing specific viscosity and working time preferences for treating vertebral compression fractures. VertaPlex HV Cement has the clearance for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty.

Features

- Immediate high viscosity after mixing
- Controlled interdigitation and fill
- Working time – approximately 18 minutes[9]
- Set time of 10.2 minutes at 37°C
- Low creep rate
- Increased viscosity improves visibility
- 30% barium sulfate concentration

VertaPlex HV Cement used in sacral vertebroplasty

Insertion of access needle using long axis approach

Injection of bone cement

VertaPlex Bone Cement

Developed for physicians who want low initial viscosity and longer working time. Advantageous for multiple level vertebroplasties and vertebral augmentations, VertaPlex Bone Cement maintains its toothpaste-like consistency for an average of 20 minutes.

Features

- Increased working time – approximately 20 minutes[9]
- Set time of 10.2 minutes at 37°C
- Low creep rate
- 30% barium sulfate concentration

SpinePlex Bone Cement

SpinePlex Bone Cement is a derivative of Simplex P Bone Cement – a widely used bone cement[22,23].
SpinePlex Cement contains the same polymethyl methacrylate (PMMA) and is manufactured using the same proprietary process as Simplex P Cement.

Features

- Working time of 10-12 minutes
- Set time of 8.2 minutes at 37°C
- 30% barium sulfate concentration

g information

À la carte

0406-622-000
(Sterile; 2 per box)
VertaPlex HV Cement
20 gram twin pack
(one-half dose)

0406-422-000
(Sterile; 2 per box)
VertaPlex Cement 20
gram twin pack
(one-half dose)

0406-222-000
(Sterile; 2 per box)
SpinePlex Cement
20 gram twin pack
(one-half dose)

Cortoss
Bone Augmentation Material

Cortoss Bone Augmentation Material is an advanced, injectable, synthetic, non-resorbable biomaterial that mimics the mechanical properties of cortical (weightbearing) bone.[24] Cortoss Material was developed to provide a bone augmentation solution for treatment of VCFs. It has been clinically proven to match the safety and effectiveness of polymethyl methacrylate (PMMA) for vertebral augmentation.[14]

Features

- Flow and fill: properties improve short-term pain and long-term function[14]
- Safety: low incidence of adjacent fractures;*[14] minimal exotherm[24] and monomer release[26]
- Control: procedural flexibility with mix-on-demand and start/stop delivery[27]
- Robust compilation of clinical data[14,28,29]

* In patients with one level treated and no previous fracture.

Multi-center clinical trials provide the proof

- The safety and efficacy of Cortoss Material have been demonstrated in several clinical investigations[28,29]
- In patients with a first-time fracture at one level, there was a 43% reduction in adjacent level fractures in the patient population using Cortoss Material (Cortoss, n=162; PMMA, n=94)[24]
- Compared to PMMA, Cortoss Material is more hydrophilic, which enables it to coat and augment the internal structure of the vertebral body; this interdigitating characteristic resulted in a 50% reduction in material injected when compared to PMMA in a controlled study[14]
- The level 1 IDE Study showed a statistically significant increase in the percentage of patients experiencing a reduction in short-term pain at three months and improvement of long-term function at 24 months[14]

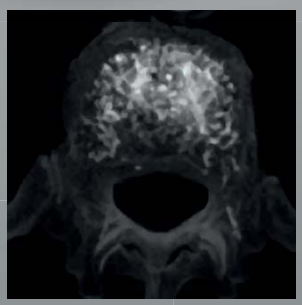
Ordering information

2110-0031
Mix-tips (3 per box)

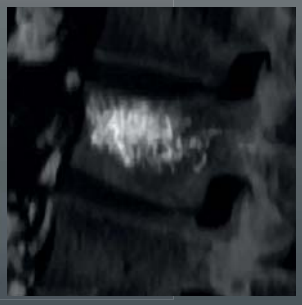
2110-0039
Delivery gun and mix tip tray

2101-0002
Cortoss Cartridge, 5cc

2101-0000
Cortoss Cartridge, 10cc


Axial view


Coronal view


Sagittal view

The bioactive response of Cortoss Material has not been assessed in any clinical investigation and the results from laboratory or animal testing may not be predictive of human clinical experience.

Mixer and delivery systems

AutoPlex
Mixer and Delivery System

Our AutoPlex Mixer and Delivery System 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

The automated blade driven mix chamber provides consistent and thorough blending of components, helping eliminate human error and variability.

Delivery

- Lightweight, ergonomic delivery injector
- Provides 12cc of deliverable cement
- Closed mixing, transfer and delivery system helps prevent exposure to harmful fumes
- Flexible extension tube and delivery cartridge, totaling 40cm in length, helps ensure radiation safety
- Easily connects to VertePort System
- Delivers 0.5cc per full turn
- Simple and reliable handheld injection

Procedure overview

Attach extension tube to delivery cartridge, pour powder and then liquid monomer through supplied funnel

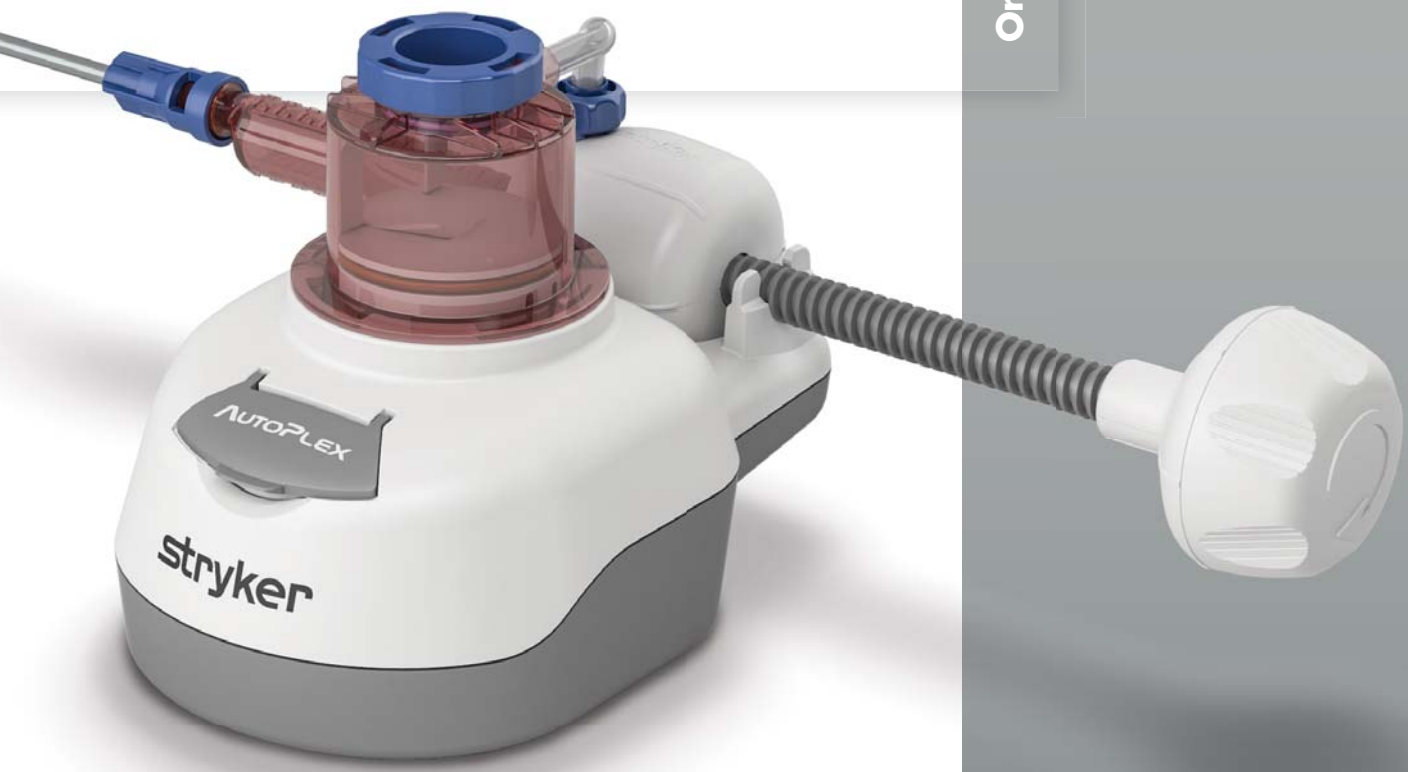
Lock lid onto mixing chamber

Press and release mixing button

Ordering information

0607-687-000
AutoPlex System with VertaPlex HV Cement (2 per box)

0605-887-000
AutoPlex System (2 per box)



Detach tube from cement injector when mixing/transfer is complete

Remove cement injector from mixing unit

PCD Mixer and Delivery System

An all-in-one mixer and delivery system, our PCD (Precision Cement Delivery) Mixer and Delivery System offers ease of use, desired cement consistency and an opportunity for improved procedural efficiency.

Mixing

- Manual mixing blade consistently blends components together to form desired viscosity in one minute
- Streamlined transfer of mixed cement to delivery cartridge

Delivery

- Hand-operated, allowing precise delivery of mixed cement with 0.4cc per full turn
- Delivery cartridge and extension tube help provide radiation safety with more than 35cm in total length
- Provides 10cc of deliverable cement

Procedure overview

Pour powder and monomer into funnel

Attach mixing blade and lock into place

Mix cement in an up-and-down motion while rotating the mixing handle

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

Ordering information

Long extension tubes

0506-486-000
PCD Kit: long 90 degree extension tube (4 per box)

0507-586-000
PCD Kit: long 90 degree extension tube and VertaPlex HV Cement (4 per box)

Short extension tubes

0506-589-000
PCD Kit: short extension tube (4 per box)

0507-589-000
PCD Kit: short extension tube and VertaPlex HV Cement (4 per box)

Lock the delivery cartridge with the extension tube attached onto the mixing chamber by rotating counter-clockwise

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

TroFlex
Curved Needle

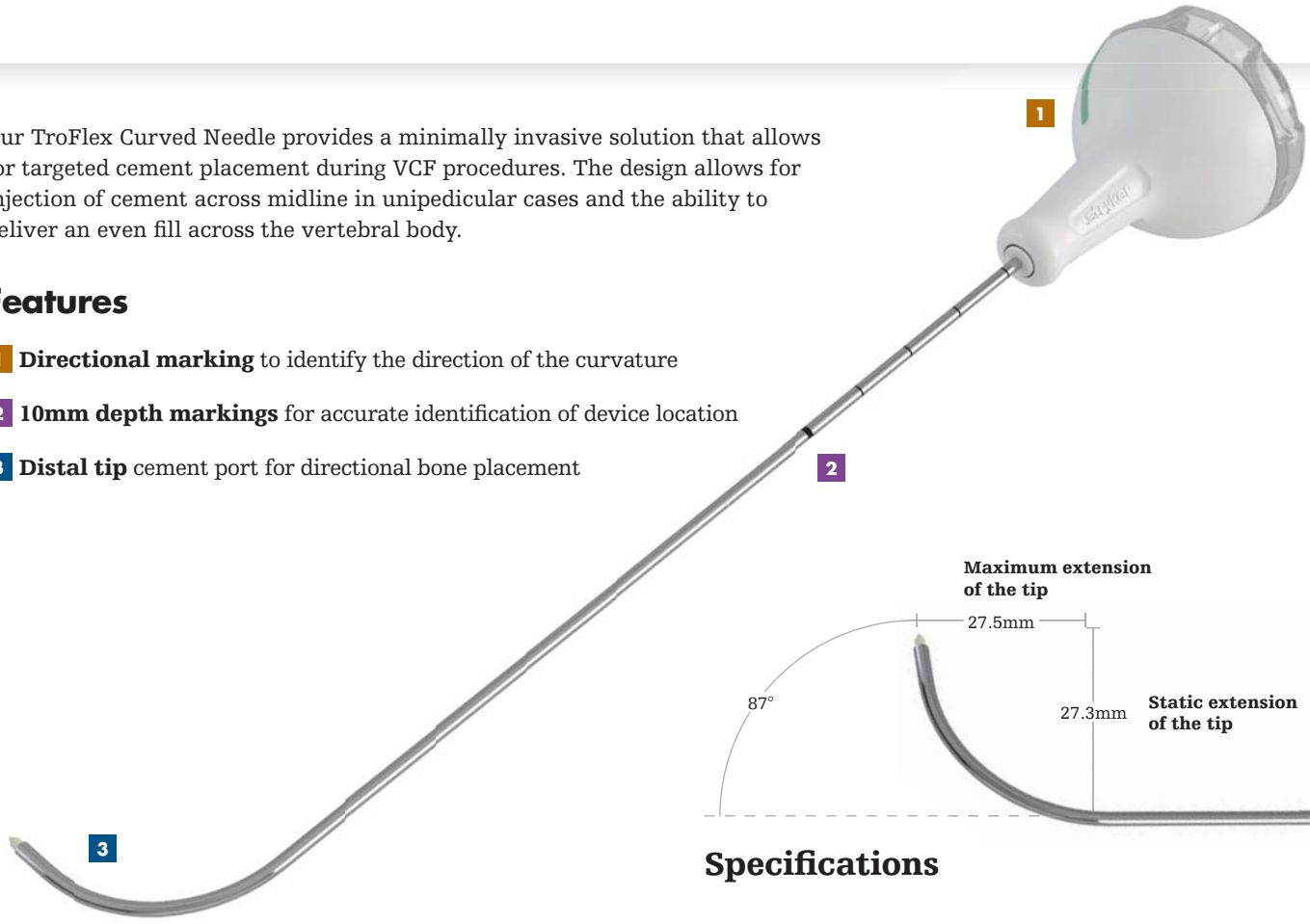
Our TroFlex Curved Needle provides a minimally invasive solution that allows for targeted cement placement during VCF procedures. The design allows for injection of cement across midline in unipedicular cases and the ability to deliver an even fill across the vertebral body.

Features

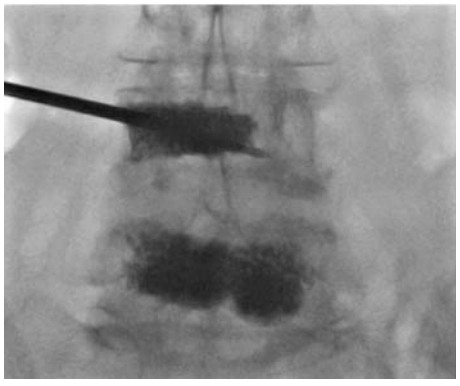
1 **Directional marking** to identify the direction of the curvature

2 **10mm depth markings** for accurate identification of device location

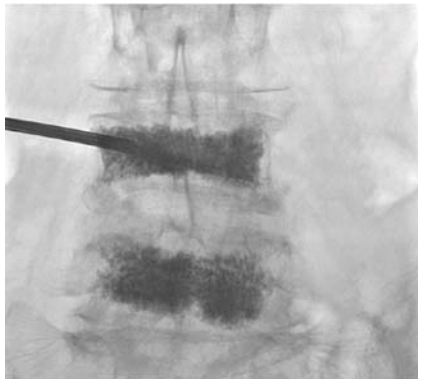
3 **Distal tip** cement port for directional bone placement



Specifications



Before TroFlex Curved Needle



After TroFlex Curved Needle

*Pictures were taken from a case performed by Dr. David Grayson of Rockingham Memorial Hospital - USA

VertePort X4 Manifold Cement Delivery Assistant

The VertePort X4 Manifold Cement Delivery Assistant is a cement-filling device for loading up to a four cement cannulae at one time, affording an opportunity for quicker and more efficient procedures.

Features

1. **Flexibility** allows one to four VertePort Cannula to be filled at the same time
2. **Standard configuration** quick connects with AutoPlex System
3. **Adapter** quick connects with PCD System
4. **Luer valves** provide smooth connect and disconnect of the cartridge
5. **Cement** only flows to loaded VertePort Cannula site
6. **Cartridge** can be used as a VertePort Cannulae stand for back-table organization

Ordering information

TroFlex Curved Needles

0306-011-000
11g TroFlex Curved Needle kit with access cannula (2 per box)

0306-011-500
TroFlex Curved Needle (2 per box)

VertePort X4 Manifold Assistant

Manifold

0605-411-000
11g VertePort Manifold (2 per box)

0605-410-000
10g VertePort Manifold (2 per box)

0605-408-000
8g VertePort Manifold (2 per box)

Cartridge

0605-411-500
11g cartridge (2 per box)

0605-410-500
10g cartridge (2 per box)

VertePort
Coaxial System

The hollow-needle VertePort Coaxial System was developed specifically for vertebral augmentation. The VertePort System offers multiple ways to deliver bone cement during VCF treatments. The VertePort Cannulae come in 8g, 10g and 11g.

Features

- Designed for precise control
- Provides constant unobstructed access to the vertebral body
- Allows for easy delivery of high viscosity bone cement
- Extends cement working time with hand obturation

Direct injection

Connecting the VertePort System to the traditional injector allows for continuous injection of cement and the potential for increased distance from radiation.

Hand obturation

When hand obturating cement, the VertePort System allows an opportunity for the delivery of thicker cement and increased working time.

Ordering information

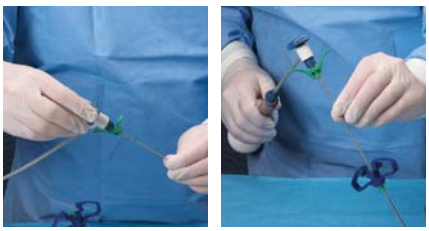
VertePort Coaxial System

0306-510-000
11g VertePort Cement Cannula (18 per box) (for use with 11g 5″ access needle 0306-110-000)

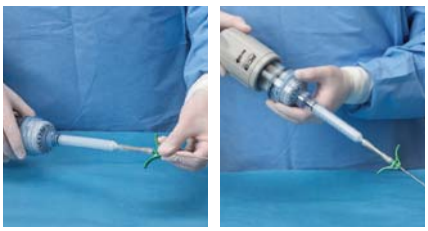
0306-410-000
10g VertePort Cement Cannula (18 per box) (for use with 10g long and short access needles 0306-400-000 and 0306-430-000)

0306-310-000
8g VertePort Cement Cannula (6 per box) (for use with 8g 5″ access needle 0306-125-000)

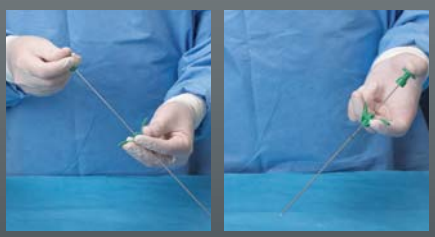
Approach overview



Coaxial delivery of cement with VertePort System



Filling of cement cannula using PCD System



Hand obturation

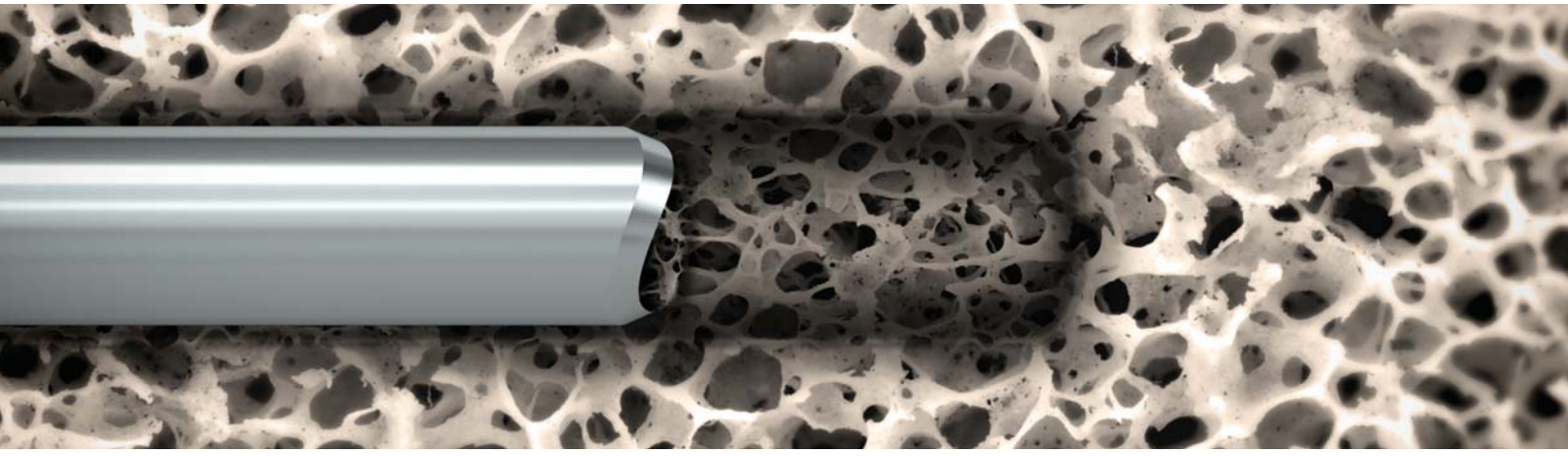
Bone biopsy
and needles

Bone Biopsy
Kits

The coaxial design of our Bone Biopsy Kits allows for collection of a core sample within the vertebral body. This streamlined technique can be used in conjunction with VCF procedures or independent biopsies. The Bone Biopsy Kit is compatible with our 8g, 10g, 11g and 13g Needles.

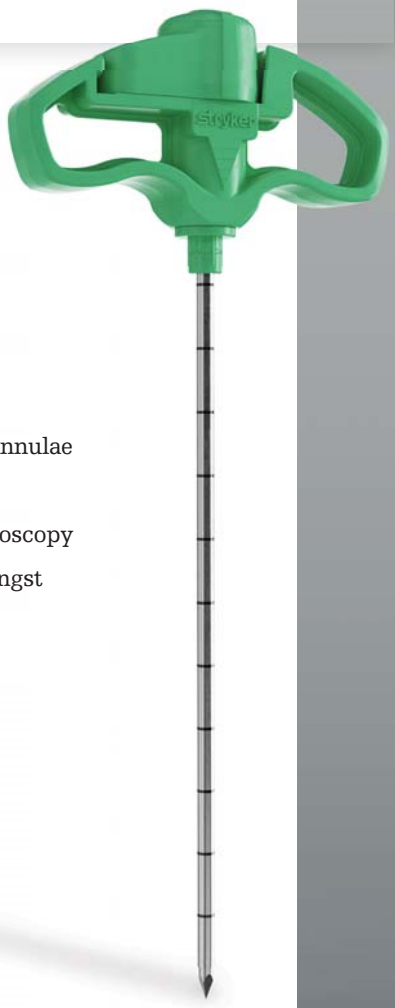
Features

- Available in 8g, 10g, 11g and 13g
- Bone Biopsy Kits for iVAS System only available in 8g, 10g and 11g
- Includes the coaxial biopsy needle, with a plunging stylet and a 3cc syringe
- Bone Biopsy Kits for iVAS System feature a rotating handle
- Bone Biopsy Kits for iVAS System increase biopsy protrusion



Sample bone biopsy

Needles

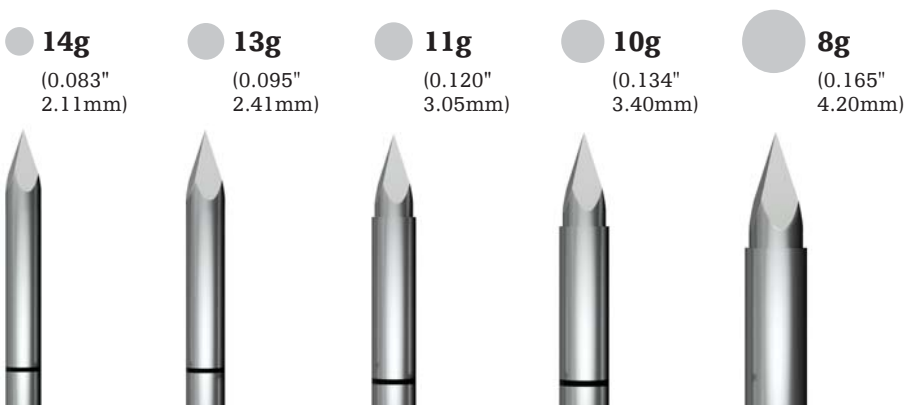


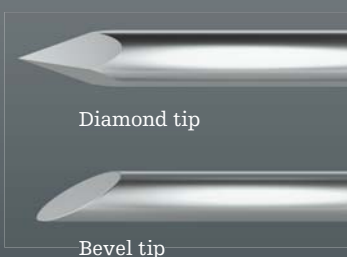
Our Needles offer control and maneuverability in accessing the vertebral body and delivering bone cement during VCF treatments. With our locking hub, we now offer greater hold torque and more rigidity than our previous generation of iVAS System Needles. These features are designed to help allow for smooth and secure needle placement while maintaining mechanical integrity.

Features

- Diamond- and bevel-tipped stylets are interchangeable with cannulae
- Wide range of gauges available: 8g, 10g, 11g, 13g and 14g
- Radiolucent handles help provide clear visibility under fluoroscopy
- Locking hub ensures security within the cannula when amongst hard cancellous bone
- Graduated markings on the 8g, 10g and 11g needles assist in measuring needle depth

Needle size comparison





Ordering information

Bone Biopsy Kits

0306-135-000
13g Bone Biopsy Kits

0306-116-000
11g iVAS Bone Biopsy Kits

0306-104-000
10g iVAS Bone Biopsy Kits

0306-195-000
10g 9″ Bone Biopsy Kits

0306-125-000
8g iVAS Bone Biopsy Kits

Needles

0306-140-000
14g 4.4″ access needle

0306-130-000
13g Access Needle

0306-131-000
13g Bevel Stylet

0306-330-000
11g iVAS Access Needle

0306-331-000
11g iVAS Bevel Stylet

0306-190-000
10g 9″ access needle

0306-191-000
10g 9″ bevel stylet

0306-530-000
10g iVAS Access Needle

0306-531-000
10g iVAS Bevel Stylet

0306-080-000
8g iVAS Access Needle

0306-081-000
8g iVAS Bevel Stylet

Ordering information

Vertebral augmentation

iVAS Balloon System kits

Each kit includes: access cannula with diamond tip stylet, bevel tip stylet, balloon catheter, inflator, syringe

0705-310-000
11g 10mm iVAS Kit (3 per box)

0705-315-000
11g 15mm iVAS Kit (3 per box)

0705-110-000
10g 10mm iVAS Kit (3 per box)

0705-115-000
10g 15mm iVAS Kit (3 per box)

0705-120-000
10g 20mm iVAS Kit (3 per box)

0705-815-000
8g 15mm iVAS Kit (3 per box)

0705-820-000
8g 20mm iVAS Kit (3 per box)

À la carte

0705-310-500
11g 10mm balloon (3 per box)

0705-315-500
11g 15mm balloon (3 per box)

0705-110-500
10g 10mm balloon (3 per box)

0705-115-500
10g 15mm balloon (3 per box)

0705-120-500
10g 20mm balloon (3 per box)

Supplemental products

0306-116-000
11g iVAS Bone Biopsy Kit
(6 per box)

0306-811-000
11g iVAS Hand Drill (6 per box)

0306-330-000
11g iVAS Access Cannula (6 per box)

0306-511-000
11g VertePort Cement Cannula
(18 per box)

0306-104-000
10g iVAS Bone Biopsy Kit
(6 per box)

0306-810-000
10g iVAS Hand Drill (6 per box)

0306-530-000
10g iVAS Access Cannula (6 per box)

0306-410-000
10g VertePort Cement Cannula
(18 per box)

0306-080-000
8g iVAS Access Cannula (6 per box)

0306-125-000
8g iVAS Bone Biopsy Kit
(6 per box)

0306-808-000
8g iVAS Hand Drill (6 per box)

0306-310-000
8g VertePort Cement Cannula
(18 per box)

AVAflex Balloon System kits

11g kit includes: access cannula with diamond tip stylet, bevel tip stylet, curved introducer loaded with peek sheath, balloon catheter, curved needle, cement introducer with touhy borst, inflator, syringe

1031-115-000
11g 15mm Vertebral Balloon System Kit (1 per box)

1031-120-000
11g 20mm Vertebral Balloon System Kit (1 per box)

1031-130-000
11g 30mm Vertebral Balloon System Kit (1 per box)

10g kit includes: access cannula with diamond tip stylet, bevel tip stylet, curved needle loaded with peek sheath, balloon catheter, cement introducer with touhy borst, inflator, syringe

1031-015-000
10g 15mm Vertebral Balloon System Kit (1 per box)

1031-020-000
10g 20mm Vertebral Balloon System Kit (1 per box)

1031-030-000
10g 30mm Vertebral Balloon System Kit (1 per box)

13g iVAS Balloon System kits

13g kit includes: access cannula with diamond tip stylet, bevel tip stylet, balloon catheter, cement introducer with touhy borst, inflator, syringe

1021-310-000
13g 10mm Single Kit (1 per box)

1021-315-000
13g 15mm Single Kit (1 per box)

1021-320-000
13g 20mm Single Kit (1 per box)

Curette

0306-621-000
11g Curette (1 per box)

0306-620-000
10g Curette (1 per box)

Implants

PMMA bone cements

À la carte

0406-622-000
(Sterile; 2 per box)
VertaPlex HV Cement 20 gram twin pack
(one-half dose)

0406-422-000
(Sterile; 2 per box)
VertaPlex Cement 20 gram twin pack
(one-half dose)

0406-222-000
(Sterile; 2 per box)
SpinePlex Cement 20 gram twin pack
(one-half dose)

Cortoss Bone Augmentation Materia

2110-0031
Mix-tips (3 per box)

2110-0039
Delivery gun and mix tip tray

2101-0002
Cortoss Cartridge, 5cc

2101-0000
Cortoss Cartridge, 10cc

Mixer and delivery systems

AutoPlex Mixer and Delivery System

0607-687-000
AutoPlex System with VertaPlex HV Cement (2 per box)

0605-887-000
AutoPlex System (2 per box)

PCD (Precision Cement Delivery) Mixer and Delivery System

0506-486-000
PCD Kit: long 90 degree extension tube (4 per box)

0507-586-000
PCD Kit: long 90 degree extension tube and VertaPlex HV Cement (4 per box)

0507-486-000
PCD Kit: long 90 degree extension tube and VertaPlex Cement (4 per box)

0506-489-000
PCD Kit: short extension tube (4 per box)

0507-589-000
PCD Kit: short extension tube and VertaPlex HV Cement (4 per box)

TroFlex Curved Needle

0306-011-000
11g TroFlex Curved Needle kit with access cannula (2 per box)

0306-011-500
TroFlex Curved Needle (2 per box)

VertePort X4 Manifold Cement Delivery Assistant

Manifold

0605-411-000
11g VertePort Manifold (2 per box)

0605-410-000
10g VertePort Manifold (2 per box)

0605-408-000
8g VertePort Manifold (2 per box)

0605-411-500
11g VertePort Cartridge (2 per box)

0605-410-500
10g VertePort Cartridge (2 per box)

VertePort Coaxial System

0306-510-000
11g VertePort Cement Cannula (18 per box) (for use with 11g 5″ access needle 0306-110-000)

0306-410-000
10g VertePort Cement Cannula (18 per box) (for use with 10g long and short access needles 0306-400-000 and 0306-430-000)

0306-310-000
8g VertePort Cement Cannula (6 per box) (for use with 8g 5″ access needle 0306-125-000)

Bone biopsy and needles

Bone Biopsy Kits

0306-125-000
8g iVAS Bone Biopsy Kit

0306-104-000
10g iVAS Bone Biopsy Kit

0306-116-000
11g iVAS Bone Biopsy Kit

0306-195-000
10g 9″ Bone Biopsy Kit

0306-135-000
13g Bone Biopsy Kit

Needles

0306-140-000
14g 4.4″ Access Needle

0306-130-000
13g Access Needle

0306-131-000
13g Bevel Stylet

0306-330-000
11g iVAS Access Needle

0306-331-000
11g iVAS Bevel Stylet

0306-190-000
10g 9″ Access Needle

0306-191-000
10g 9″ bevel stylet

0306-530-000
10g iVAS Access Needle

0306-531-000
10g iVAS Bevel Stylet

0306-080-000
8g iVAS Access Needle

0306-810-000
8g iVAS Bevel Stylet

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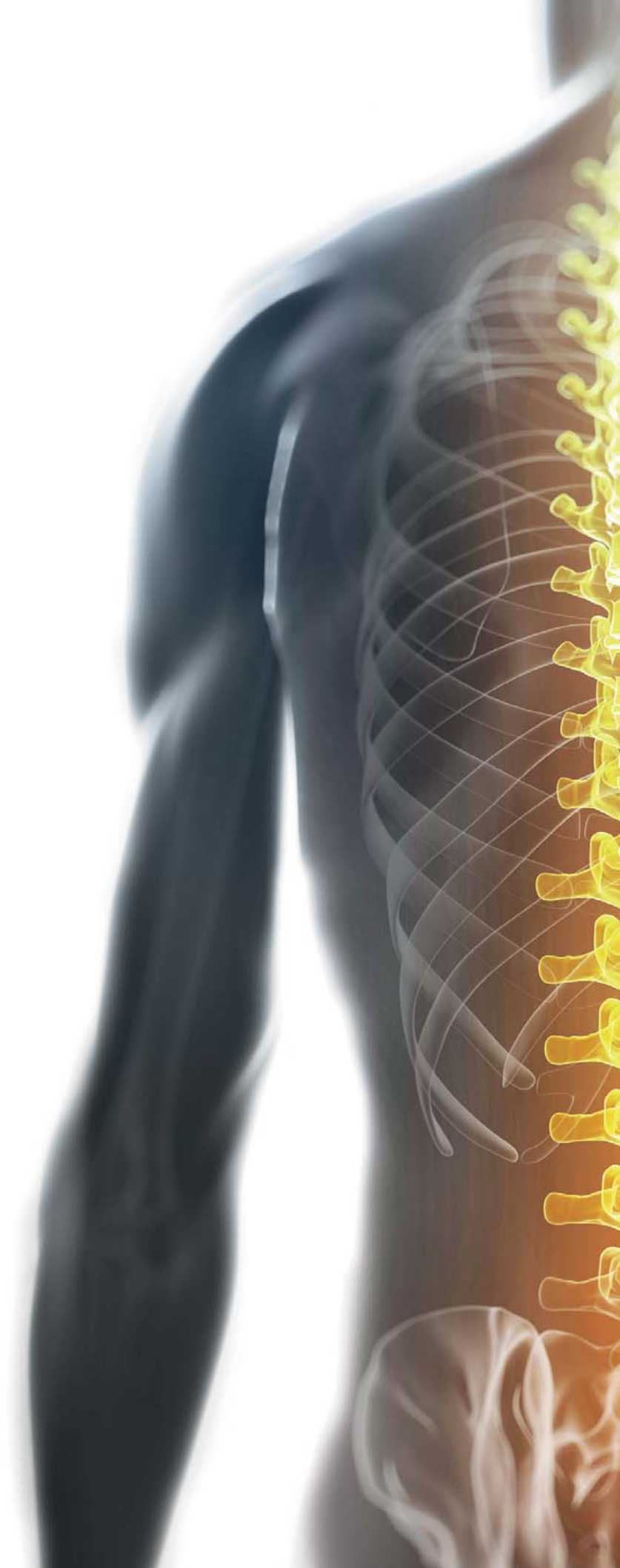

Interventional Spine

Complications are rare. Serious adverse events, some with fatal outcome, associated with the use of bone cements for vertebroplasty, kyphoplasty and sacroplasty include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism and cardiac embolism. Although it is rare, some adverse events have been known to occur up to one year post-operatively. Additional risks exist with the use of bone cement. Please see the IFU for a complete list of potential risks.

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