

Medtronic

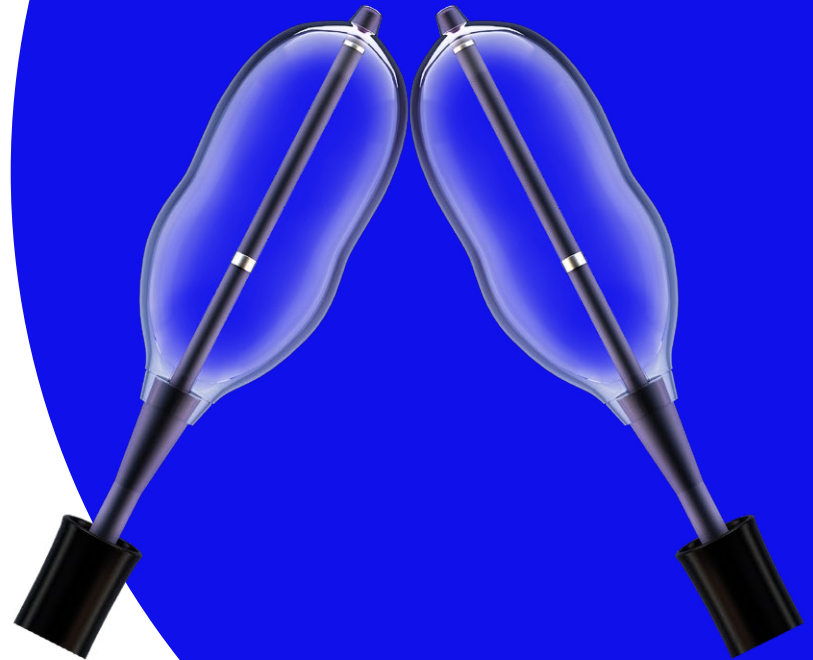
Engineering the extraordinary

Performance you can count on

The Kyphon™ balloon
kyphoplasty (BKP) portfolio

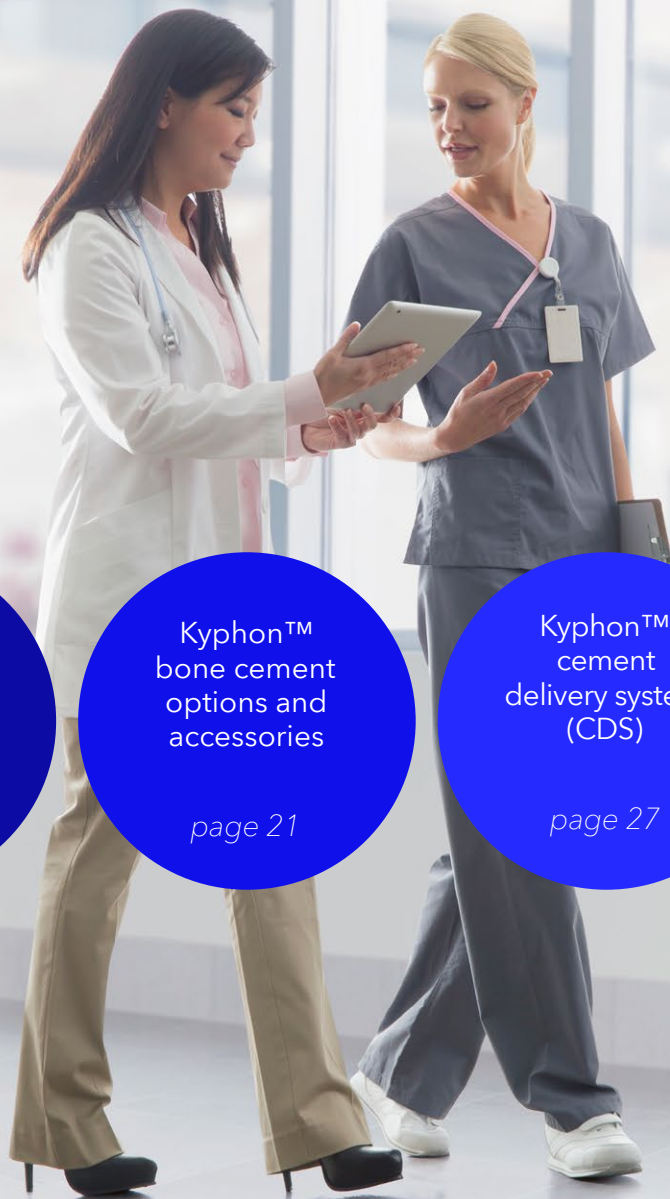
Get started >

Providing more for you and your VCF patients.



Kyphon™ balloon kyphoplasty (BKP) provides MORE breakthrough solutions for you, your patients, and your procedure. Together, we can transform how vertebral compression fractures are treated.

Physicians have used Kyphon™ BKP to treat more than 1.8 million vertebral fractures.¹



Kyphon Express™ II
10 ga system

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Kyphon Xpander™ II
8 ga system

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Kyphon™ bone cement
options and
accessories

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delivery system
(CDS)

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Get started



More for you and your patients

More force

Kyphon Xpander™ II and Kyphon Express™ II inflatable bone tamps are rated to 700 psi, allowing greater lift force for vertebral body fracture reduction.²

More technique flexibility

The cement resistance technique helps preserve intraoperative vertebral body fracture reduction by allowing cement delivery to contact the inflated balloon on the contralateral side.

More reduction in radiation

Reduce your hand radiation exposure by more than 70% using the Kyphon™ cement delivery system, which allows you to stand up to 4 feet away from the radiation source.**

More control

A quick-release button halts cement flow instantly² to minimize the potential for cement extravasation. Each full squeeze of the lever ejects approximately 0.2 cc of bone cement.

More choices

Treat more spine levels and improve your procedural flexibility with our broad portfolio of tools.³ A variety of bone cements offers choices for minimally invasive injection into vertebrae.

*Maximum rated inflation pressure (unilateral vs. bilateral approach – KyphX Xpander 15/3 IBTs)

** Compared to Kyphon™ bone filler device, when measured with dosimeters under fluoroscopy. Mean radiation reduction at the hands was reduced 77.79% (P < 0.001), based on internal testing of 24 total cadaveric procedures (Kyphon CDS: n=12; Kyphon™ bone filler device: n=12). Dosimeters placed on the wrist and fingers measured radiation while bone cement was delivered into the vertebral body. Radiation results are based on procedures as directed by the Directions For Use.

Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

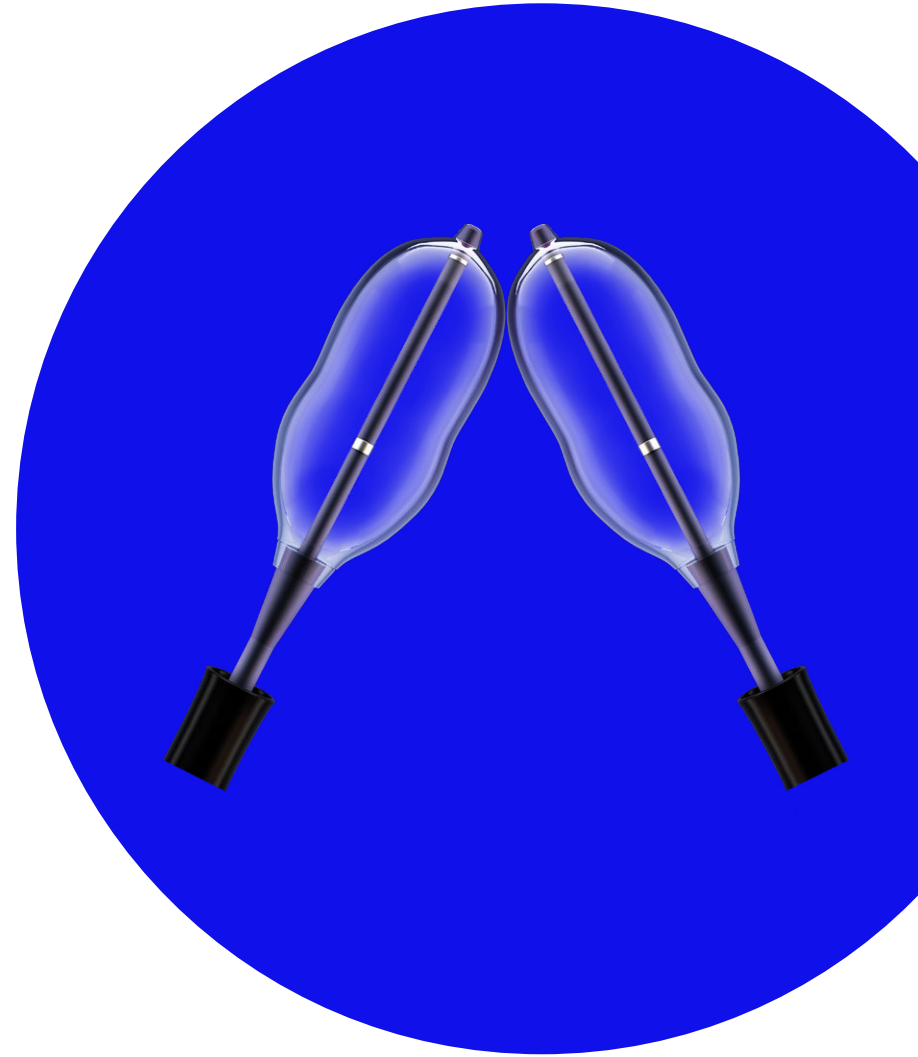
Instrument size
and conversion
tables

Kyphon Express™ II 10 ga system

Bone access tools and inflatable bone tamps (IBTs) for fracture reduction – size 2, 10 gauge tapered

Experience more

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Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Express™ II 10 ga system

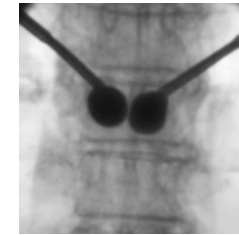
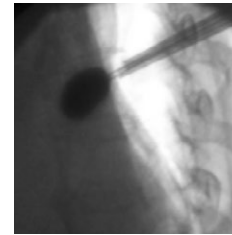
Overview

Expanded portfolio

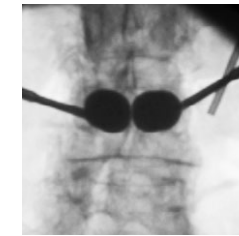
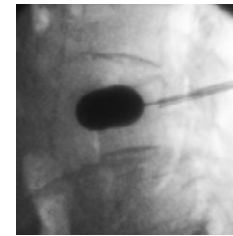
The Kyphon Express™ II balloon kyphoplasty (BKP) platform offers the choice of 10 mm, 15 mm, and 20 mm balloons, providing more procedural flexibility. Physicians can choose the length and volume option most appropriate for the individual patient, vertebral body, and fracture.

Cement resistance technique

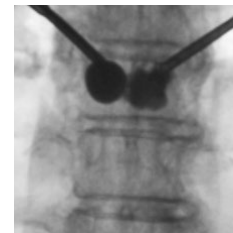
Kyphon Express™ II balloons are monomer-resistant for up to 5 minutes, allowing physicians to maintain inflation of one balloon while delivering PMMA-based bone cement on the contralateral side. See the “cement resistance technique” outlined in the product’s Instructions For Use.



10/2 in T9



20/2 in L4



Kyphon Express™ II 10/2
with 2 cc of PMMA-based bone
cement



Kyphon Express™ II 10/2
with 3 cc of PMMA-based bone
cement

Kyphon Express™ II 10 ga system

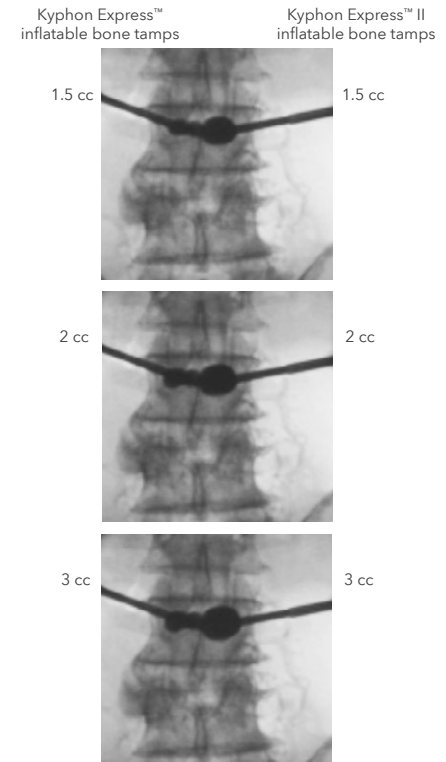
Overview

Higher performance

The Kyphon Express™ II balloons have maximum pressure ratings of 700 psi, allowing continued inflation when encountering resistance, while our previous balloons have maximum pressure ratings of 400 psi.

Power of 2

In addition to higher pressure ratings, the bilateral approach to balloon kyphoplasty offers more lift force. In bench testing comparing the bilateral approach to the unilateral approach, the bilateral approach yielded 200% lift force and 26% less stress on the endplate.⁴



Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Express™ II 10 ga system

Product specifics: Introducer options

Kyphon Express™ Osteo Introducer™ system (T34A)
Diamond, bevel, and drill

Osteo Introducer™ device, diamond (T34D)



Osteo Introducer™ device, bevel (T34E)



Osteo Introducer™ device, trocar (T34B)



Advanced Osteo Introducer™ device (T34C)



Drill (T34F)



Bone biopsy device (F07A)



Kyphon Express™ II 10 ga system

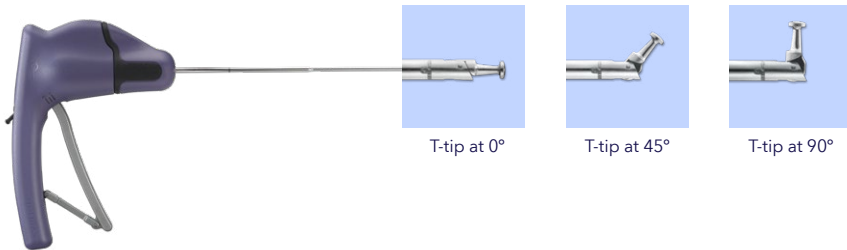
Product specifics: Curette options

Kyphon Express™ curette

Procedural options for interventional treatment of vertebral compression fractures

Spinal fracture reduction procedures may pose obstacles such as pockets of harder bone (compared to surrounding areas). Kyphon™ curettes offer physicians the ability to scrape and score bone within the vertebral body to assist in void creation, including in balloon kyphoplasty procedures.

For use with the Kyphon Express™ and Express™ II (10 ga) systems, the Kyphon Express™ curette features a robust T-tip that locks at 0, 45, and 90 degrees as well as an integrated torque reset mechanism to limit excess torsion (and, thus, the potential for tip breakage) and maximize procedure efficiency.



Features

Lever handle with locking mechanism and degree indicator	<ul style="list-style-type: none"> Comfortable trigger handle for precise control Locks tip at 0°, 45°, and 90° Use in the unlocked position provides free movement from 0° to 90° Indicates angle of tip deployment
T-tip	<ul style="list-style-type: none"> Symmetrical cone design facilitates uniform scoring action in all directions Rounded tip surface designed for smooth sweeping and scoring action
Tethered tip	<ul style="list-style-type: none"> Dual tip attachment mechanism (pivot pin plus UniLink actuator loop) for durability and control
Torque-limiting features	<ul style="list-style-type: none"> Torque reset mechanism on the express curette transfers any excess torsion encountered at the tip to the handle, allowing the device to be reset and reused
Shaft exit marker	<ul style="list-style-type: none"> Exit marker on shaft aligns with proximal end of cannula to indicate when curette tip is at distal edge of cannula

Ordering information

Kyphon Express™ Curette, use with Kyphon Express™ Systems (10 ga, size 2)

ITEM #	DESCRIPTION
A13A	Kyphon Express™ Curette, 7 mm T-tip

Kyphon Express™ II
10 ga system

Kyphon Xpander™ II
system

Kyphon™ bone
cement options
and accessories

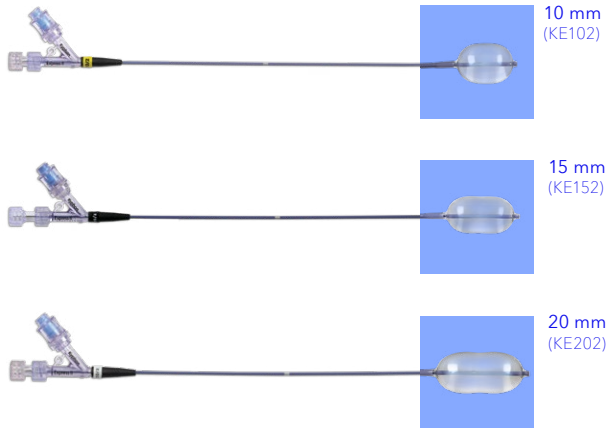
Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Express™ II 10 ga system

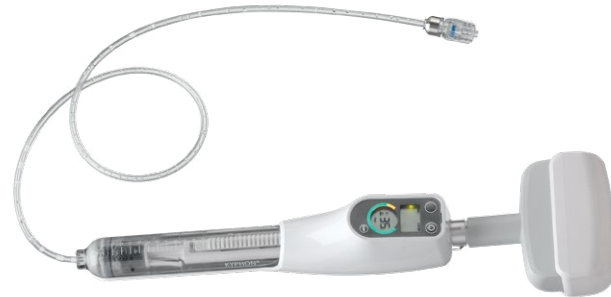
Product specifics: Balloon options

Kyphon Express™ II inflatable bone tamps



IBT size	Initial length (mm)	Max volume (cc)	Pressure (psi)
10/2	10	3	700
15/2	15	4	700
20/2	20	5	700

Kyphon™ inflation syringe (A08E)



Kyphon Express™ II
10 ga system

Kyphon Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Express™ II 10 ga system

Product specifics: Kits and part numbers

Bone access and biopsy devices

Part code	Product description
T34A	Kyphon Express™ Osteo Introducer™ System (Diamond, Bevel, Drill)
T34B	Kyphon Express™ Osteo Introducer™ Device, Trocar
T34C	Kyphon Express™ Advanced Osteo Introducer™ Device
T34D	Kyphon Express™ Osteo Introducer™ Device, Diamond
T34E	Kyphon Express™ Osteo Introducer™ Device, Bevel
T34F	Kyphon Express™ Osteo Introducer™ Device, Drill
F07A	Kyphon Express™ Bone Biopsy Device

Cement and cement delivery

Part code	Product description
C01A	Kyphon™ HV-R™ Bone Cement
C01B	Kyphon™ HV-R™ Bone Cement and Kyphon™ Mixer Pack
CX01B	Kyphon™ Xpede™ Bone Cement and Kyphon™ Mixer Pack
C10A	Kyphon™ ActivOs™ 10 Bone Cement (order with A07A mixer)
CDS2A	Kyphon™ Cement Delivery Gun and Bone Filler Device
CC02A	Kyphon™ CDS Cement Cartridges
F06A	Kyphon Express™ Bone Filler Device
F06B	Kyphon Express™ Directional Bone Filler Device

KyphoPak trays | Kit components and options

Catalog no.	Description	First fracture	Additional fracture	T34A	KE102	KE152	KE202	FO6A	A08E	CC02A	CDS2A
KEX102EB	KyphoPak™ Tray, 10/2 IBT, Kyphon Express™ II Osteo Introducer™ System	✓		1	2			8	2		
KEX102EB-CDS	KyphoPak™ Tray, 10/2 IBT, Kyphon Express™ II Osteo Introducer™ System with CDS System Bundle	✓		1	2				2	1	1
KEX102NB	KyphoPak™ Tray, 10/2 IBT, Kyphon™ Additional Fracture		✓		2			8			
KEX152EB	KyphoPak™ Tray, 15/2 IBT, Kyphon Express™ II Osteo Introducer™ System	✓		1		2		8	2		
KEX152EB-CDS	KyphoPak™ Tray, 15/2 IBT, Kyphon Express™ II Osteo Introducer™ System with CDS System Bundle	✓		1		2			2	1	1
KEX152NB	KyphoPak™ Tray, 15/2 IBT, Kyphon™ Additional Fracture		✓			2		8			
KEX202EB	KyphoPak™ Tray, 20/2 IBT, Kyphon Express™ II Osteo Introducer™ System	✓		1			2	8	2		
KEX202EB-CDS	KyphoPak™ Tray, 20/2 IBT, Kyphon Express™ II Osteo Introducer™ System with CDS System Bundle	✓		1			2		2	1	1
KEX202NB	KyphoPak™ Tray, 20/2 IBT, Kyphon™ Additional Fracture		✓				2	8			

Kyphon Express™ first-generation (400 psi rated) a la carte and kit options

Part code	Product description
KE102	Kyphon Express™ II Inflatable Bone Tamp, 10/2
KE152	Kyphon Express™ II Inflatable Bone Tamp, 15/2
KE202	Kyphon Express™ II Inflatable Bone Tamp, 20/2
K15A	Kyphon Express™ Inflatable Bone Tamp, 10/2
K15B	Kyphon Express™ Inflatable Bone Tamp, 15/2
KPE1001	KyphoPak™ Express™ Tray, 10/2 IBT, Kyphon Express™ Osteo Introducer™ System
KPE1001-CDS	KyphoPak™ Express™ Tray, 10/2 IBT, Kyphon Express™ Osteo Introducer™ with CDS System
KPE1002	KyphoPak™ Express™ Tray, 10/2 IBT, Kyphon™ Additional Fracture
KPE1003	KyphoPak™ Express™ Tray, 15/2 IBT, Kyphon Express™ Osteo Introducer™ System
KPE1003-CDS	KyphoPak™ Express™ Tray, 15/2 IBT, Kyphon Express™ Osteo Introducer™ with CDS System
KPE1004	KyphoPak™ Express™ Tray, 15/2 IBT, Kyphon™ Additional Fracture
A08E	Kyphon™ Inflation Syringe with locking syringe
A13A	Kyphon Express™ Curette

Kyphon Express™ II
10 ga system

Kyphon Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Xpander™ II 8 ga system

Bone access tools and inflatable bone tamps (IBTs)
for fracture reduction – size 3, 8 gauge

Expect more

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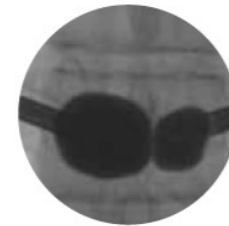
Kyphon Xpander™ II 8 ga system

Overview

Greater strength

The Kyphon Xpander™ II inflatable bone tamp (IBT), or balloon, redefines the standard for “strength” in balloon technology: This IBT has more power and withstands higher forces during inflation.⁵

- **Increased structural integrity** – Because of strengthened bonds and modified co-extrusion methods, the Kyphon Xpander™ II IBT has greater structural integrity and offers greater lift force capability.⁵
- **Level T10 cadaver test:**
 - Left pedicle: Kyphon Xpander™ II IBT, Size 10/3, at 3.5 cc and 500 psi
 - Right pedicle: Kyphon Xpander™ II IBT, Size 10/3, at 2.0 cc and 400 psi
- **More hoop strength** – The Kyphon Xpander™ II balloon’s material contains greater hoop strength, and its hoop strength increases with volume. Increased hoop stress allows the balloon shape to remain unchanged in a more variable inflation environment.⁶



A less compliant balloon material prevents the balloon from deforming due to increased stronger hoop strength.

Kyphon Xpander™ II 8 ga system

Expanded control

Engineered with a stronger, more structured balloon material, the Kyphon Xpander™ II balloon offers greater predictability to give you better control when it counts.⁵

- **Improved, predetermined shape** – Designed with a “less compliant” material, the Kyphon Xpander™ II balloon is less likely to enter into the path of least resistance, offering you more control during inflation and an improved, predetermined shape.⁵
- **Patented balloon design** – The Kyphon Xpander™ II balloon has a patented balloon design that inflates with a distinct “waist.” Its thickened waist helps control inflation pattern, dispersing lift force across and minimizing concentrated stresses against the contact area.
- **Controlled radial lift force** – The balloon design offers radial lift force while controlling surface contact stresses.



Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Xpander™ II 8 ga system

Higher performance

The Kyphon Xpander™ II balloon can resist PMMA-based cements' chemical reaction while it remains inflated, allowing you to keep the balloon inflated during contra-lateral cement fill.

- **Maintain inflation during contralateral cement fill** – When following the “cement resistance technique” outlined in the Instructions For Use, you can keep the balloon inflated during a contralateral cement fill.²
- **More lift force** – The bilateral approach to balloon kyphoplasty offers more lift force. In bench testing comparing the bilateral approach to the unilateral approach, the bilateral approach yielded 200% lift force and 26% less stress on the endplate.⁴



Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

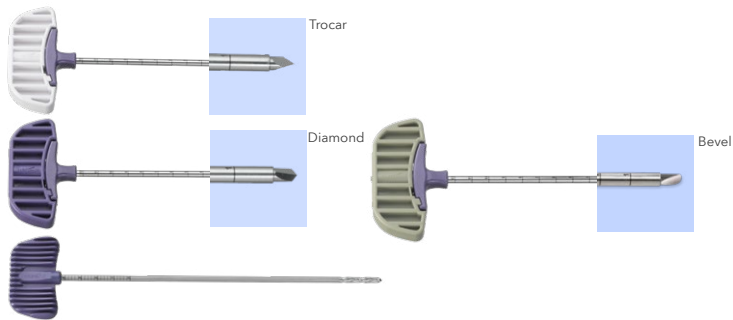
Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

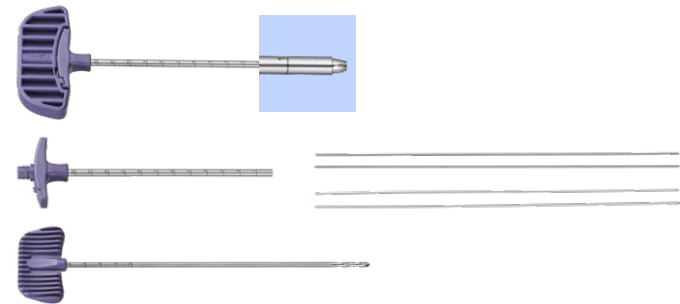
Kyphon Xpander™ II 8 ga system

Product specifics: Introducer options

One-Step™ Osteo Introducer™ system
*Trocar and diamond tips, drill (T15J)
bevel (T15K)*



Osteo Introducer™ system (T15D)
Osteo Introducer™ and cannula, drill, guide wires



Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

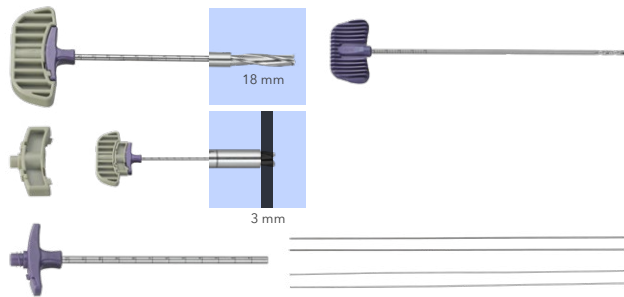
Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

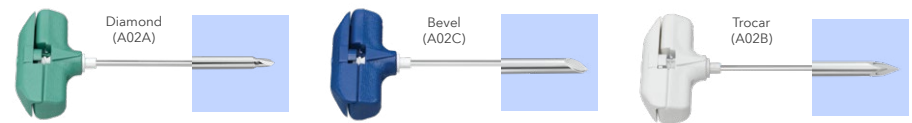
Kyphon Xpander™ II 8 ga system

Product specifics: Introducer options

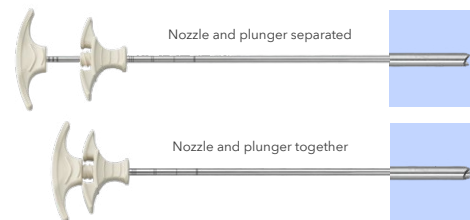
Advanced™ Osteo Introducer™ System (T15E)
Advanced Osteo Introducer™ device and cannula (A20A), drill, guide wires



11 ga bone access needles
*Diamond (A02A)
Trocar (A02B)
Bevel (A02C)*



Bone biopsy device, size 3 (F05A)



Kyphon Xpander™ II 8 ga system

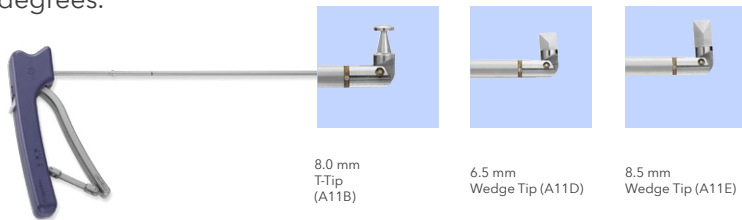
Product specifics: Curette options

Kyphon™ Latitude™ II curette

Procedural options for interventional treatment of vertebral compression fractures

Spinal fracture reduction procedures may pose obstacles such as pockets of harder bone (compared to surrounding areas). Kyphon™ curettes offer physicians the ability to scrape and score bone within the vertebral body to assist in void creation, including in balloon kyphoplasty procedures.

The Kyphon™ Latitude™ II curette is compatible with Kyphon Xpander™ and Xpander™ II (8 ga) systems and offers multiple tip types and sizes to meet balloon kyphoplasty procedural needs and a range of features to improve function and usability. Tips lock at 0, 30, 60, and 90 degrees.



Features

Lever handle with locking mechanism and degree indicator	<ul style="list-style-type: none"> Comfortable trigger handle for precise control Locks tip at 0°, 30°, 60°, and 90° Use in the unlocked position provides free movement from 0° to 90° Indicates angle of tip deployment
T-tip	<ul style="list-style-type: none"> Symmetrical cone design facilitates uniform scoring action in all directions Rounded tip surface designed for smooth sweeping and scoring action
Wedge tip (Latitude II only)	<ul style="list-style-type: none"> Narrow profile facilitates tip articulation and deployment Designed for scoring grooves or channels
Tethered tip	<ul style="list-style-type: none"> Dual tip attachment mechanism (pivot pin plus UniLink actuator loop) for durability and control
Torque-limiting features	<ul style="list-style-type: none"> Score line on shaft of the Latitude™ II curette disengages when excess torsion is encountered, allowing the device to be safely removed
Shaft exit marker	<ul style="list-style-type: none"> Exit marker on shaft aligns with proximal end of cannula to indicate when curette tip is at distal edge of cannula
Cannula stop (Latitude II only)	<ul style="list-style-type: none"> Collar on shaft provides physical stop to prevent curette tip from extending more than 3.7 cm past distal edge of cannula

Ordering information

Kyphon™ Latitude™ II Curette, use with Kyphon Xpander™ Systems (8 ga, size 3)

Item #	Description
A11B	Kyphon Latitude II Curette, 8.0 mm T-tip
A11D	Kyphon Latitude II Curette, 6.5 mm Wedge tip
A11E	Kyphon Latitude II Curette, 8.5 mm Wedge tip

Kyphon Express™ II 10 ga system

Kyphon Xpander™ II system

Kyphon™ bone cement options and accessories

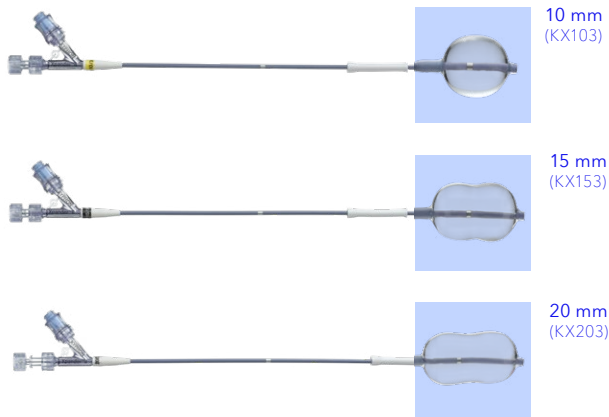
Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon Xpander™ II 8 ga system

Product specifics: balloon options

Kyphon Xpander™ II inflatable bone tamps



IBT size	Initial length (mm)	Max volume (cc)	Pressure (psi)
10/3	10	4	700
15/3	15	5	700
20/3	20	6	700

Kyphon™ inflation syringe (A08E)



Kyphon
Express™ II
10 ga system

Kyphon
Xpander™ II
system

Kyphon™ bone
cement options
and accessories

Kyphon™ cement
delivery system
(CDS)

Instrument size
and conversion
tables

Kyphon Xpander™ II 8 ga system

Product specifics: Kits and part numbers

Catalog no.	Description	First fracture	Additional fracture Kyphon™ 11 ga Bone access needle	T15D	T15E	T15J	KX103	KX153	KX203	F04B	A08E	CC02A	CD53A
KPX103RB	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Osteo Introducer™ System	✓	2	1			2			6	2		
KPX103RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Osteo Introducer™ with CDS System	✓	2	1			2			2	1	1	
KPX103AB	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	✓	2	1			2			6	2		
KPX103AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System	✓	2	1			2			2	1	1	
KPX103NB	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ additional Fracture		✓				2			6			
KPX103PB	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	✓				1	2			6	2		
KPX103PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ One-Step Osteo Introducer™ with CDS System	✓				1	2			2	1	1	
KPX153RB	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Osteo Introducer™ System	✓	2	1			2			6	2		
KPX153RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Osteo Introducer™ with CDS System	✓	2	1			2			2	1	1	
KPX153AB	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	✓	2	1			2			6	2		
KPX153AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System	✓	2	1			2			2	1	1	

Catalog no.	Description	First fracture	Additional fracture Kyphon™ 11 ga Bone access needle	T15D	T15E	T15J	KX103	KX153	KX203	F04B	A08E	CC02A	CD53A
KPX153NB	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ additional Fracture		✓						2	6			
KPX153PB	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	✓				1		2		6	2	1	1
KPX153PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ One-Step Osteo Introducer™ with CDS System	✓				1		2		2			
KPX203RB	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Osteo Introducer™ System	✓	2	1					2	6	2	1	1
KPX203RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Osteo Introducer™ with CDS System	✓	2	1					2	2			
KPX203AB	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	✓	2	1					2	6	2	1	1
KPX203AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System	✓	2	1					2	2			
KPX203NB	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ additional Fracture		✓						2	6			
KPX203PB	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	✓				1			2	6	2		
KPX203PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ One-Step Osteo Introducer™ with CDS System	✓				1			2	2	1	1	

Kyphon Express™ II 10 ga system

Kyphon Xpander™ II system

Kyphon™ bone cement options and accessories

Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon Xpander™ II 8 ga system

Product specifics:
Kits and part numbers

Ordering information

Kyphon™ Latitude™ II Curette, use with
Kyphon Xpander™ Systems (8 ga, size 3)

Item #	Description
A11B	Kyphon Latitude II Curette, 8.0 mm T-tip
A11D	Kyphon Latitude II Curette, 6.5 mm Wedge tip
A11E	Kyphon Latitude II Curette, 8.5 mm Wedge tip

Kyphon Xpander™ first-generation (400 psi rated) kit configurations

Catalog no.	Description	First fracture	Additional fracture	Kyphon™ 11 ga bone access needle	T15D	T15E	T15J	K13A	K09A	K08A	F04B	A08A	C002A	C053A
KPT1002	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ Osteo Introducer™ System	✓		2	1			2			6	2		
KPT1002-CDS	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ Osteo Introducer™ With CDS System	✓		2	1			2				2	1	1
KPT1003	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon Advanced™ Osteo Introducer™ System	✓		2		1		2			6	2		
KPT1003-CDS	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon Advanced™ Osteo Introducer™ With CDS System	✓		2		1		2				2	1	1
KPT1004	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ Additional Fracture		✓					2			6			
KPT1005	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon One-Step™ Osteo Introducer™ System	✓					1	2			6	2		
KPT1005-CDS	Kyphopak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon One-Step™ Osteo Introducer™ With CDS System	✓					1	2				2	1	1
KPT1502	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ Osteo Introducer™ System	✓		2	1				2		6	2		
KPT1502-CDS	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ Osteo Introducer™ With CDS System	✓		2	1				2			2	1	1
KPT1503	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon Advanced™ Osteo Introducer™ System	✓		2		1			2		6	2		
KPT1503-CDS	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon Advanced™ Osteo Introducer™ With CDS System	✓		2		1			2			2	1	1
KPT1504	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ Additional Fracture		✓						2		6			
KPT1505	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon One-Step™ Osteo Introducer™ System	✓					1		2		6	2		
KPT1505-CDS	Kyphopak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon One-Step™ Osteo Introducer™ With CDS System	✓					1		2			2	1	1
KPT2002	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ Osteo Introducer™ System	✓		2	1					2	6	2		
KPT2002-CDS	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ Osteo Introducer™ With CDS System	✓		2	1					2		2	1	1
KPT2003	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon Advanced™ Osteo Introducer™ System	✓		2		1				2	6	2		
KPT2003-CDS	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon Advanced™ Osteo Introducer™ With CDS System	✓		2		1				2		2	1	1
KPT2004	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ Additional Fracture		✓							2	6			
KPT2005	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon One-Step™ Osteo Introducer™ System	✓					1			2	6	2		
KPT2005-CDS	Kyphopak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon One-Step™ Osteo Introducer™ With CDS System	✓					1			2		2	1	1

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Kyphon™ bone cement options and accessories

Cement solutions for interventional treatment of vertebral compression fractures

More options, more control

- Xpede cement 22
- HV-R cement 23
- ActivOs™ 10 cement 24
- Kyphon cement mixer & multi-tap adapter 25
- Cement, mixer, & multi-tap part numbers 26



Kyphon™ bone cement options and accessories

Kyphon Xpede™ bone cement

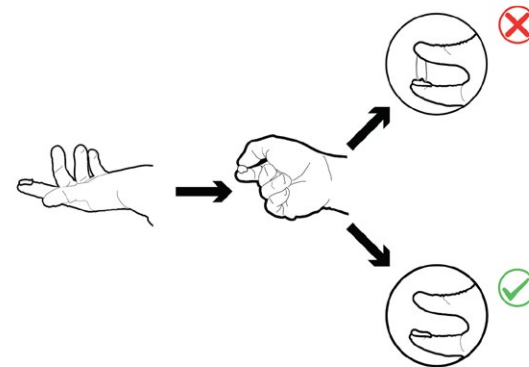
Procedure efficiency and flexibility

This “quick-to-dough” cement rapidly reaches an appropriate viscosity for injection into a fractured vertebra, thereby reducing waiting time. Kyphon Xpede™ also possesses a long working time, allowing flexibility in handling during an interventional procedure.

Using Kyphon Xpede™ bone cement with Kyphon™ CDS (cement delivery system) allows the physician to deliver highly viscous bone cement from up to 48 inches away from the radiation source while still maintaining tactile feel.³

Average room temperature at start of mixing (±1°C)	Average dough time (minutes)	Average hardening time (minutes)	Average working period (minutes)
15	12.8	42.8	30.0
19	5.8	21.9	16.1
23	2.4	15.8	13.4
26	2.0	13.3	11.3

Bone cement readiness technique



Under specific conditions in our laboratory using the Kyphon™ cement delivery system (CDS), Kyphon Xpede™ bone cement, had the above dough time, hardening time, and working period, which allowed sufficient time for careful, minimally invasive surgical introduction of the bone cement. Lower temperatures or other changes in operating room conditions can increase the handling, working (doughy), and hardening periods. Conversely, higher temperatures or other changes in operating room conditions can decrease the handling, working (doughy), and hardening periods.

Kyphon Express™ II 10 ga system

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Kyphon™ bone cement options and accessories

Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon™ bone cement options and accessories

Kyphon HV-R™ bone cement

First cement designed for balloon kyphoplasty

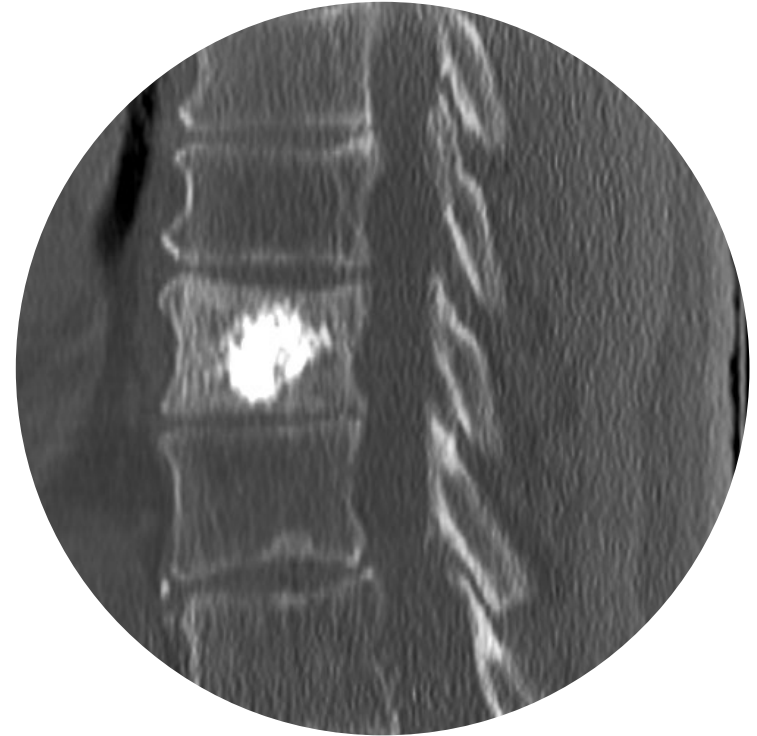
Kyphon HV-R™ bone cement was the first bone cement FDA-cleared for use in the spine. It's designed to meet the specific needs of the balloon kyphoplasty procedure by providing for the controlled delivery of highly viscous bone cement.

Timing of HV-R mixing, dough, hardening, and average working period are dependent on the average room temperature.

Average room temperature at start of mixing (±1°C)	Average dough time (minutes)	Average hardening time (minutes)	Average working period (minutes)
15	23.8	40.0	16.2
19	14.0	33.8	19.8
22	9.5	17.9	8.4
23	8.9	19.3	10.4
25	7.6	18.4	10.8
29	4.6	12.3	7.7

Radiopaque PMMA bone cement

Like other injectable bone cements, Kyphon HV-R™ bone cement is PMMA-based and contains 30% barium sulfate, providing visibility under fluoroscopy.



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Kyphon Xpander™ II system

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Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon™ bone cement options and accessories

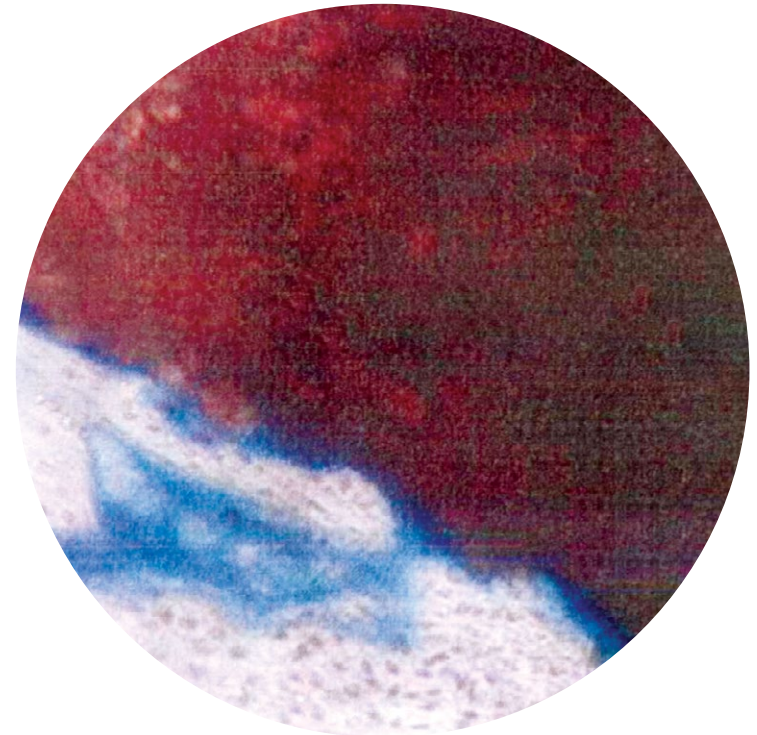
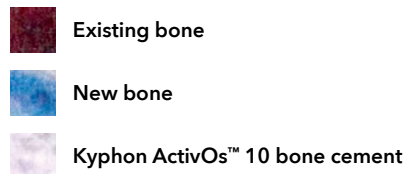
Kyphon ActivOs™ 10 bone cement with hydroxyapatite

Kyphon ActivOs™ 10 bone cement, the biomimetic choice for your balloon kyphoplasty procedures, is formulated with 10% hydroxyapatite (HA) by weight in the powder. HA is⁷:

- Chemically and structurally similar to the mineral component of bone
- Widely used in dental and orthopedic implants
- Highly radiopaque

Why hydroxyapatite? Animal testing, which is not indicative of human clinical outcomes, showed⁸:

- New bone formation on the surface of the cement
- No intervening fibrous tissue layer formation
- No inflammatory response



Kyphon Express™ II 10 ga system

Kyphon Xpander™ II system

Kyphon™ bone cement options and accessories

Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon™ bone cement options and accessories

Kyphon™ mixer and Kyphon™ multi-tap adapter

The Kyphon™ multi-tap adapter streamlines the balloon kyphoplasty procedure by reducing the number of steps required to dispense PMMA-based cements. The adapter attaches to the Kyphon™ mixer and enables all Kyphon™ bone filler devices to be filled simultaneously. The Kyphon™ multi-tap adapter can be utilized with Xpede™, HV-R™ and ActivOs™ 10 cements.



Kyphon Express™ II 10 ga system

Kyphon Xpander™ II system

Kyphon™ bone cement options and accessories

Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon™ bone cement options and accessories

Cement, mixer, and multi-tap part numbers

Part no.	Product name
CX01B	Kyphon Xpede™ Bone Cement with Mixer
C10A	Kyphon ActivOs™ 10 Bone Cement with Hydroxyapatite
C01A	Kyphon HV-R™ Bone Cement
C01B	Kyphon HV-R™ Bone Cement with Mixer
A07A	Kyphon™ Mixer
A22	Kyphon™ Multi-tap Adapter for use with Kyphon Express™ (10 ga) bone filler devices
A23	Kyphon™ Multi-tap Adapter for use with Kyphon Xpander™ (8 ga) bone filler devices
CX01B-MT2	Kyphon Xpede™ Bone Cement with Mixer and Kyphon™ Multi-tap Adapter (A22)
CX01B-MT3	Kyphon Xpede™ Bone Cement with Mixer and Kyphon™ Multi-tap Adapter (A23)

Kyphon™ cement delivery system (CDS)

Interventional treatment of vertebral compression fractures

More precision, less exposure

CDS overview 28
Product specifics: CDS part numbers 29



Kyphon Express™ II 10 ga system

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Kyphon™ bone cement options and accessories

Kyphon™ cement delivery system (CDS)

Instrument size and conversion tables

Kyphon™ cement delivery system (CDS)

Overview

Precisely controlled bone cement delivery from up to 4 feet away from the radiation source.³

Less exposure

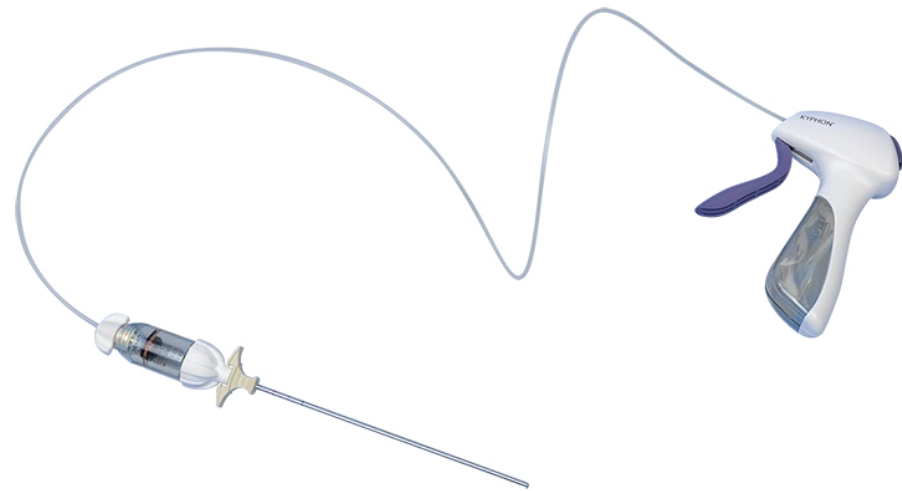
- Allows the physician to deliver highly viscous bone cement from up to 48 inches away from the radiation source while maintaining tactile feel
- Reduced hand radiation exposure by more than 70%*

Precise control

- Quick-release button halts cement flow instantly
- Each full squeeze of the gun lever ejects approximately 0.2 cc of bone cement

Procedure efficiency

- Ability to simultaneously fill two cement cartridges (8 cc per cartridge) with T-adapter
- Smooth, transparent cement cartridges with high-contrast markings for better readability



*Compared to Kyphon™ bone filler device, when measured with dosimeters under fluoroscopy. Mean radiation reduction at the hands was reduced 77.79% (P < 0.001), based on internal testing of 24 total cadaveric procedures (Kyphon™ CDS: n = 12; Kyphon™ bone filler device: n = 12). Dosimeters placed on the wrist and fingers measured radiation while bone cement was delivered into the vertebral body. Radiation results are based on procedures as directed by the Directions For Use.

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Product specifics: CDS part numbers

Kyphon Express™ II CDS kits		Kyphon Express™ CDS kits		CDS a la Carte options	
ITEM #	DESCRIPTION	ITEM #	DESCRIPTION	ITEM #	DESCRIPTION
KEX102EB-CDS	KyphoPak™ Express™ II Tray, 10/2 IBT, Kyphon™ Express™ II Osteo Introducer™ System with CDS System	KPE1001-CDS	KyphoPak™ Express™ Tray, 10/2 IBT, Kyphon™ Express™ Osteo Introducer™ with CDS System	CDS3A	Kyphon™ Cement Delivery Gun and Bone Filler Devices (2), Size 3 (compatible with Kyphon Xpander and Xpander II Systems)
KEX152EB-CDS	KyphoPak™ Express™ II Tray, 15/2 IBT, Kyphon™ Express™ II Osteo Introducer™ System with CDS System	KPE1003-CDS	KyphoPak™ Express™ Tray, 15/2 IBT, Kyphon™ Express™ Osteo Introducer™ with CDS System	CDS2A	Kyphon™ Cement Delivery Gun and Bone Filler Devices (2), Size 2 (compatible with Kyphon Express and Express II Systems)
KEX202EB-CDS	KyphoPak™ Express™ II Tray, 20/2 IBT, Kyphon™ Express™ II Osteo Introducer™ System with CDS System			CC02A	Kyphon™ CDS Cement Cartridges (2-pack)

Kyphon Xpander™ II CDS kits		Kyphon Xpander™ CDS kits		Cement options	
ITEM #	DESCRIPTION	ITEM #	DESCRIPTION	ITEM #	DESCRIPTION
KPX103RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Osteo Introducer™ System	KPT1002-CDS	KyphoPak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ Osteo Introducer™ with CDS System	CX01B	Kyphon™ Xpede™ Bone Cement with Mixer
KPX103AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	KPT1003-CDS	KyphoPak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System	C10A	Kyphon™ ActivOs™ 10 Bone Cement
KPX103PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 10/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	KPT1005-CDS	KyphoPak™ Tray, Kyphon Xpander™ 10/3 IBT, Kyphon™ One-Step™ Osteo Introducer™ with CDS System	C01A	Kyphon™ HV-R™ Bone Cement
KPX153RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Osteo Introducer™ System	KPT1502-CDS	KyphoPak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ Osteo Introducer™ with CDS System	C01B	Kyphon™ HV-R™ Bone Cement with Mixer
KPX153AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	KPT1503-CDS	KyphoPak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System	A07A	Kyphon™ Mixer
KPX153PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 15/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	KPT1505-CDS	KyphoPak™ Tray, Kyphon Xpander™ 15/3 IBT, Kyphon™ One-Step™ Osteo Introducer™ with CDS System		
KPX203RB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Osteo Introducer™ System	KPT2002-CDS	KyphoPak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ Osteo Introducer™ with CDS System		
KPX203AB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ Advanced Osteo Introducer™ System	KPT2003-CDS	KyphoPak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ Advanced Osteo Introducer™ with CDS System		
KPX203PB-CDS	KyphoPak™ Tray, Kyphon XPANDER™ II 20/3 IBT, Kyphon™ One-Step Osteo Introducer™ System	KPT2005-CDS	KyphoPak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ One-Step™ Osteo Introducer™ with CDS System		
KPT2005-CDS	KyphoPak™ Tray, Kyphon Xpander™ 20/3 IBT, Kyphon™ One-Step™ Osteo Introducer™ with CDS System				

Kyphon Express™ II 10 ga system

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Instrument size and conversion tables

Instrument size and conversion tables

Conversion table

Gauge	O.D.	I.D.	O.D.	I.D.
	Inches		Millimeters	
15	0.072	0.054	1.829	1.372
14	0.083	0.063	2.108	1.600
13	0.095	0.071	2.413	1.803
12	0.109	0.085	2.769	2.159
11	0.120	0.094	3.048	2.388
10	0.134	0.106	3.404	2.692
9	0.148	0.118	3.759	2.997
8	0.165	0.135	4.191	3.429
7	0.180	0.150	4.572	3.810
6	0.203	0.173	5.156	4.394

1 inch = 25.4 mm
 1 mm = 0.04 inch = 3 French
 I.D. = Inner diameter
 O.D. = Outer diameter

Instrument size chart

Access	Gauge	O.D.	I.D.
		Millimeters	
Working Cannula, standard size 3	7-8	4.293	3.733
Kyphon™ Advanced™, Osteo Introducer™, and Kyphon One-Step™ Stylet	9-10	3.505	-
Kyphon Express™ Working Cannula (Proximal End)	7	4.572	4.064
Kyphon Express™ Working Cannula (Distal End)	9-10	3.429	2.921
Kyphon Express™ Osteo Introducer™ Stylet (Proximal End)	9-10	3.505	-
Kyphon Express™ Osteo Introducer™ Stylet (Distal End)	12-13	2.692	-
Fracture reduction			
Kyphon Xpander™ II and Xpander™ Inflatable Bone Tamp Shaft	12-13	2.591	-
Kyphon™ Exact™ Inflatable Bone Tamp Shaft	10	3.404	-
Kyphon™ Latitude™ II Curette Shaft	10	3.404	-
Kyphon Express™ II and Express™ Inflatable Bone Tamp Shaft	14-15	2.032	-
Kyphon Express™ Curette Shaft (Proximal/Distal End)	10/12-13	3.404/2.743	-
Fill			
Kyphon™ Bone Filler Device/Bone Biopsy Device Nozzle	10	3.404	2.896
Kyphon™ Bone Filler Device/Bone Biopsy Device Plunger	12	2.769	-
Kyphon Express™ Bone Filler Device/Bone Biopsy Device Nozzle (Proximal End)	9	3.759	3.251
Kyphon Express™ Bone Filler Device/Bone Biopsy Device Nozzle (Distal End)	13	2.413	1.905
Kyphon Express™ Proximal Plunger	11	3.048	-
Kyphon Express™ Distal Plunger	15	1.829	-

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Disclosure

Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. The overall complication rate with the procedure has been demonstrated to be low. Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, cardiac embolism. For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions For Use included with the product.

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References

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2. Medtronic data on file. Kyphon Xpander™ II and Kyphon Express™ II inflatable bone tamps IFU M708348B326 Rev. B.
3. Medtronic data on file. Kyphon™ cement delivery system IFU M708348B358 Rev. A.
4. Medtronic data on file. ETR31100034: Unilateral vs. bilateral BKP; 2010.
5. Medtronic data on file. ETRxxxx Internal testing in a cadaver model comparing Kyphon Xpander™ II IBT to Kyphon Xpander™ IBT; 2010. ("Stronger" as defined by Kyphon Xpander™ II balloon's greater "hoop strength" compared to that of Kyphon Xpander™ balloon. "More structured" is explained by the Kyphon Xpander™ II balloon's less compliant balloon material compared to that of Kyphon Xpander™ IBT.)
6. Based on theoretical values only.
7. LeGeros. Properties of osteoconductive biomaterials: calcium phosphates. *Clinical orthopaedics and related research*. 2002;395:81-98.
8. Medtronic data on file. Histological analysis report of rabbit femurs – HA cement in animal study; 2010.

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