



IZI Medical

# Osteo-site®

Vertebroplasty and Bone Biopsy

Minimally Invasive  
Spine Solutions

2019 Product Catalog



IZI Medical

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## NEEDLES

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IZI Medical

# Introducing IZI Medical Products.

In May 2017, IZI Medical Products acquired the vertebroplasty platform of products from Cook Medical.

Based outside of Baltimore, Maryland, IZI Medical Products is a leading developer, manufacturer, and provider of high-quality medical devices used in interventional radiology, radiation therapy, and image guided surgical procedures.

The Murphy needle, developed in collaboration with Dr. Kieran Murphy and introduced in 2000 has set the standard for percutaneous entry needles globally.

*“We are ready for a new era in Vertebroplasty. IZI Medical Products will offer new product development, a unique and broader cement offering, and new initiatives with doctors”*

Greg Groenke  
CEO, IZI Medical Products

Welcome to your minimally invasive spine solutions partner.

## Did you know?

- Estimated 850,000<sup>1</sup> patients globally have been diagnosed or treated with the help of the Osteo-Site needles
- Osteoporotic VCFs affect an estimated 1.4 million patients in the world annually<sup>2</sup>
- 1/3 women over 50 will experience osteoporotic fractures. As will 1/5 men<sup>3</sup>
- Osteoporosis affects Quality of Life. Besides the pain, patients also express anxiety about the possibility of future fractures and physical deformity<sup>4</sup>
- It is estimated that over 200 million people worldwide have osteoporosis<sup>5</sup>
- First Vertebroplasty procedure was in 1987: Galibert P, Deramond H, Rosat P, Le Gars D. Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty. Neurochirurgie. 1987;33:166-8

# Osteo-Site<sup>®</sup> Needles

## Features & Benefits



### Ergonomic Handle Design

Of the cannula enabling positive experience and maximum performance



### Sharpened Cutting Tip

Outer cannula has a sharpened cutting tip to maintain access for biopsy and infusion when inner stylet is removed



### Radiolucent Handle

Which provides an unobstructed view during introduction into bone, ensuring accurate needle placement



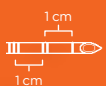
### The Sharp Diamond-Tipped Stylet

Facilitates easy placement into the periosteum and bone cortex



### The 30° Side-Beveled Stylet

For minor redirection of needle during introduction



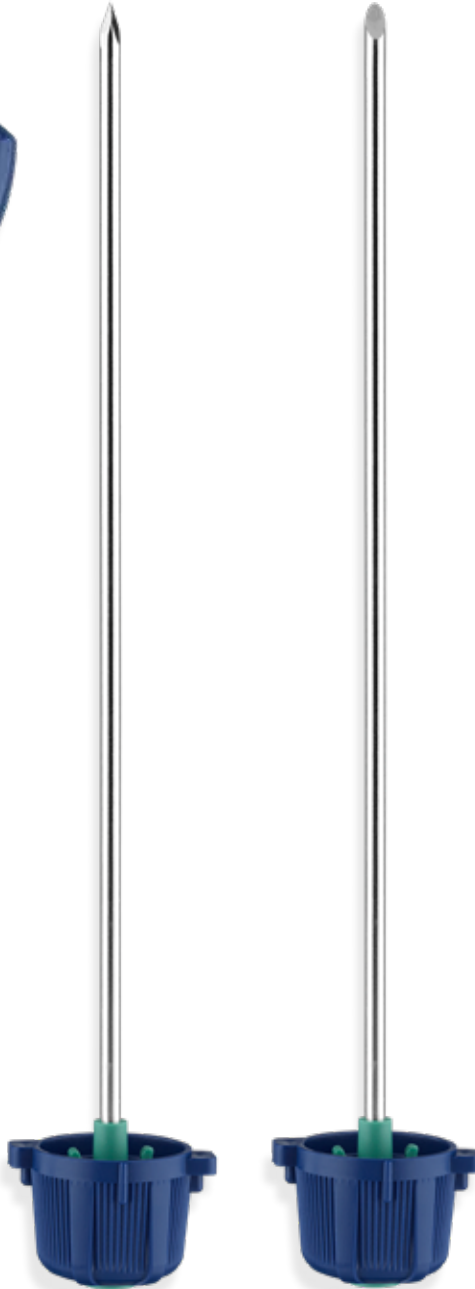
### 1 cm Increments

Outer cannula is marked with 1 cm increments in order to help guide and gauge depth



### Radiolucent Needle-Holder

Certain sets include a 20 cm radiolucent needle-holder



Osteo-Site® Products / Needles

# Bone Biopsy Needle Set

## Side-bevel and diamond-tip

Used for vertebral body biopsy and infusion

- ◇ 2 inner stylets featuring 1 side-beveled and 1 diamond shaped tip
- ◇ A blunt tip stainless steel obturator is included

Supplied sterile in peel-open packages. Intended for one-time use only.

Gain access for **biopsy and injection** with side-bevel and diamond-tip stylets

The side-bevel allows the physician to **direct the needle** to the desired location

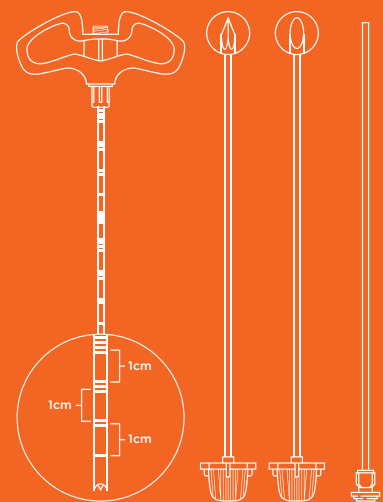
The diamond-tip **facilitates easy placement** into the periosteum and bone cortex



### ORDER INFORMATION

#### Bone Biopsy Needle Set

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-11-10.0	11G • 10 cm	G12373
DBBN-11-15.0	11G • 15 cm	G12374
DBBN-13-10.0	13G • 10 cm	G12499
DBBN-13-15.0	13G • 15 cm	G12500



Not all parts numbers shown may be approved for sale in all regulatory jurisdictions. Parts and configurations are subject to change without notification. Please consult with your Account Representative for details.



Osteo-Site® Products / Needles

# Murphy M1M™ - Side-Bevel

## Bone Biopsy Needle Set

Used for vertebral body biopsy and infusion

- ◇ Inner stylet and outer cannula are side-beveled to match
- ◇ A blunt tip stainless steel obturator is included
- ◇ A 20 cm long radiolucent needle holder is included

Supplied sterile in peel-open packages. Intended for one-time use only.

To achieve **improved purchase** on the periosteum, the outer cannula is back-beveled

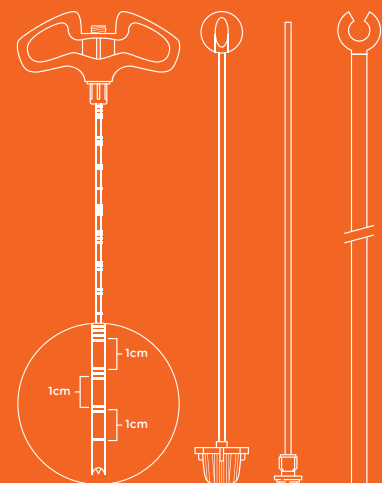
The side-bevel allows the physician to **direct the needle** to the desired location



### ORDER INFORMATION

#### Murphy M1M™ - Side-Bevel

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-11-10.0-M1M	11G • 10 cm	G13761
DBBN-11-15.0-M1M	11G • 15 cm	G26949
DBBN-13-10.0-M1M	13G • 10 cm	G13762
DBBN-13-15.0-M1M	13G • 15 cm	G26950
<b>SPECIAL SIZE</b>		
DBBN-11-18.0-M1M	11G • 18 cm	G27000



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Osteo-Site® Products / Needles

# Murphy M2™ - Diamond-tip

## Bone Biopsy Needle Set

Used for vertebral body biopsy and infusion

- Inner stylet is ground to match the trephine tip of the depth-marked outer cannula
- A blunt tip stainless steel obturator is included
- A 20 cm long radiolucent needle holder is included

Supplied sterile in peel-open packages. Intended for one-time use only.

The matched stylet/cannula tips **maximize access** and biopsy capabilities

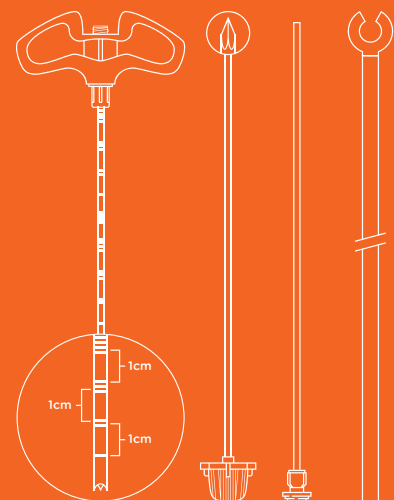
The sharp diamond-beveled tip **provides optimum purchase** on the vertebral body



### ORDER INFORMATION

#### Murphy M2™ - Diamond-tip

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-11-10.0-M2 ○	11G • 10 cm	G13018
DBBN-11-15.0-M2 ○	11G • 15 cm	G13020
DBBN-13-10.0-M2 ○	13G • 10 cm	G13019
DBBN-13-15.0-M2 ○	13G • 15 cm	G13021



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Osteo-Site® Products / Needles

# Murphy M2-S™ - Multi-Purpose Set

## Coaxial Bone Biopsy Needle Set

Used for vertebral body biopsy and infusion

- Includes a high-torque steel inner biopsy needle with trephine tip
- A blunt tip stainless steel obturator is included
- A 20 cm long radiolucent needle holder is included

Supplied sterile in peel-open packages. Intended for one-time use only.

Access, biopsy and cement injection – all with a **single access point**

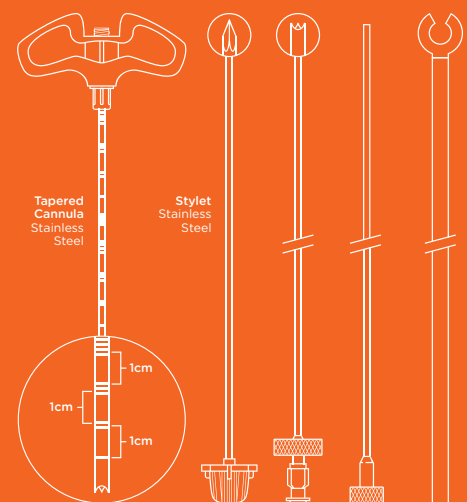
The inner needle is **introduced coaxially** through the depth-marked Osteo-Site needle



### ORDER INFORMATION

#### Murphy M1M™ - Side-Bevel

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	INNER BIOPSY NEEDLE GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-11-10.0-M2-S	11G • 10 cm	14G • 17.1 cm	G36211
DBBN-11-15.0-M2-S	11G • 15 cm	14G • 22.1 cm	G36406
DBBN-13-10.0-M2-S	13G • 10 cm	16G • 17.1 cm	G36407
DBBN-13-15.0-M2-S	13G • 15 cm	16G • 22.1 cm	G36409



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Osteo-Site® Products / Needles

# Martin Cervical Bone Biopsy Needle Set

## Side-bevel and diamond-tip

Used for vertebral body biopsy and infusion

- Inner stylet and depth-marked outer cannula are side-beveled to match
- A blunt tip stainless steel obturator is included
- A 20 cm long radiolucent needle holder is included

Supplied sterile in peel-open packages. Intended for one-time use only.

To achieve **improved purchase** on the periosteum the outer cannula is back-beveled

The 15 gauge needle allows **less traumatic access** into small bone



### ORDER INFORMATION

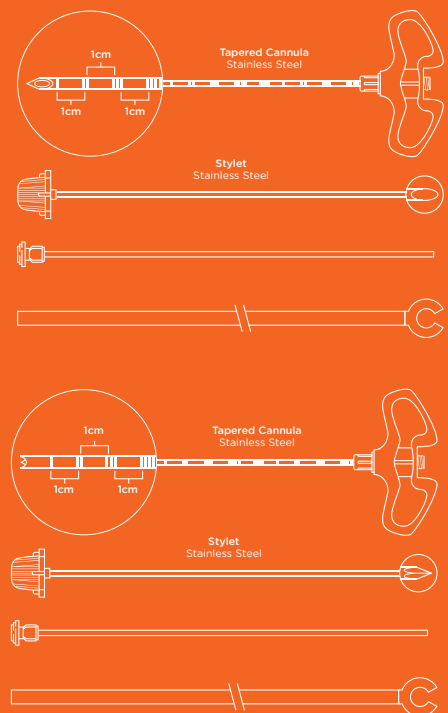
#### Martin Cervical Bone Biopsy Needle Sets with Side-Bevel Tip

SET ORDER NUMBER	OUTER CANNULA: GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-15-10.0-CERV	15G • 10 cm	G26951
DBBN-15-15.0-CERV	15G • 15 cm	G55028

#### Martin Cervical Bone Biopsy Needle Sets with M2™ Diamond Tip

SET ORDER NUMBER	OUTER CANNULA: GAUGE • LENGTH	GLOBAL PROD. NO.
DBBN-15-10.0-M2-CERV	15G • 10 cm	G55029
DBBN-15-15.0-M2-CERV	15G • 15 cm	G55030

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Osteo-Site® Products / Needles

# Coaxial Curved Bone Biopsy Needle Set

## Side-bevel

Used for vertebral body biopsy and infusion

- Inner stylet and depth-marked outer cannula are side-beveled to match
- A curved needle with a flexible stylet are included
- A blunt tip stainless steel obturator and curved needle obturator are included

Supplied sterile in peel-open packages. Intended for one-time use only.

The curved needle allows **directional infusion** of bone cement into the vertebral body

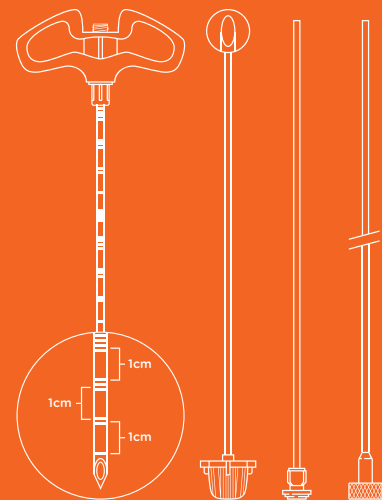
Reach the entire vertebral body via a **unipedicular approach** with the curved needle option



### ORDER INFORMATION

#### Coaxial Curved Bone Biopsy Needle Set

SET ORDER NUMBER	INTRODUCER NEEDLE GAUGE • LENGTH	CURVED NEEDLE GAUGE • LENGTH	GLOBAL PROD. NO.
DCBNS-13-19.0-C	10G • 10 cm	13G • 19 cm	G13053



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Osteo-Site® Products / Needles

# Coaxial Bone Biopsy Needle Set

## Trephine tip

Used for the coaxial biopsy

- Outer cannula features trephine tip to ease access
- Compatible with any standard Osteo-Site® outer cannula size (11 or 13 gauge)
- A blunt tip stainless steel obturator is included

Supplied sterile in peel-open packages. Intended for one-time use only.

Allows **coaxial biopsy during bone access** and infusion procedures

Choose **individual devices** to fit your specific procedure



### ORDER INFORMATION

#### Coaxial Bone Biopsy Needle Set

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
DCBBN-14-17.1	14G • 17.1 cm	G24315
DCBBN-14-22.1	14G • 22.1 cm	G24316
DCBBN-16-17.1	16G • 17.1 cm	G24317
DCBBN-16-22.1	16G • 22.1 cm	G24318



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Osteo-Site® Products / Needles

# Ratchet Bone Biopsy Needle Set

## Hand Drilling Into Hard Bone

Used for vertebral body biopsy and infusion

- Ratchet-style unidirectional drilling action and unique spade tip design
- A blunt tip stainless steel obturator is included

Supplied sterile in peel-open packages. Intended for one-time use only.

Hand control allows **smooth drilling** while reducing risk of incidental loss of pressure or direction

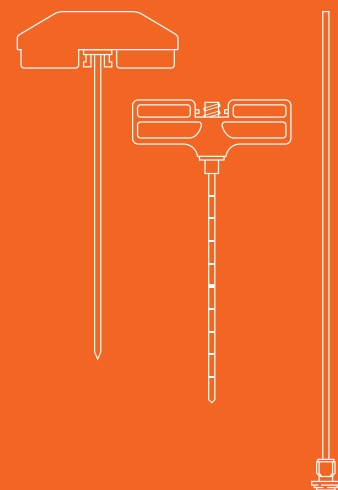
Quiet drilling operation can maintain **patient comfort**



### ORDER INFORMATION

#### Ratchet Bone Biopsy Needle Set

SET ORDER NUMBER	OUTER CANNULA GAUGE • LENGTH	GLOBAL PROD. NO.
RBBN-11-10.0	11G • 10 cm	G24311
RBBN-11-15.0	11G • 15 cm	G24312
RBBN-13-10.0	13G • 10 cm	G24313
RBBN-13-15.0	13G • 15 cm	G24314



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# Osteo-Site<sup>®</sup> Cement Features & Benefits

An Innovative Range of PMMA Bone Cements  
Indicated for Vertebroplasty and kyphoplasty

- Premeasured one-to-one ratio components (polymer & monomer) ready-to-use and easy to mix
- Low or medium viscosity enabling sufficient injection time (From 10 to 20 min)
- High rate of radiopaque agent providing safe radiological control

## Indications

	VERETEX PLUS	OSTEOFIX	THERMALFIX
VERTEBROPLASTY	●	●	●
KYPHOPLASTY	●	●	●

## Features

MIXED VOLUME	16CC	16CC	16CC
RADIOPACITY	35%	45%	50%
MAX TEMPATURE	59° C / 138.2° F	40° C / 104.0° F	88° C / 190.4° F
VISCOSITY	LOW	MEDIUM	LOW
MIXING TIME	30 SEC	30 SEC	45 SEC
TRANSFER TIME	1.5 MIN	5.5 MIN	2.25 MIN
WAITING TIME	2 MIN	0 MIN	0 MIN
INJECTION TIME	8 MIN	15.5 MIN	9.5 MIN
MECHANICAL PROPERTIES	COMPLIANT W/ISO 5833	COMPLIANT W/ISO 5833	COMPLIANT W/ISO 5833



Osteo-Site® Products / Cements

# Vertefix® Plus

## Biocompatible Bone Cement

Used for fixation of pathological fractures of the vertebral body using vertebroplasty and kyphoplasty procedures, as well as injection into pedicular screws.

- Two components (powder & liquid) PMMA bone cement
- Cement components are easy to mix, no measurement is required
- Injection time: 8 minutes. Yield: 16 cc of PMMA

Supplied sterile in box. Intended for one-time use.



### DELIVERY TECHNIQUE

**Osteo-Site® Needle**

### SIZE

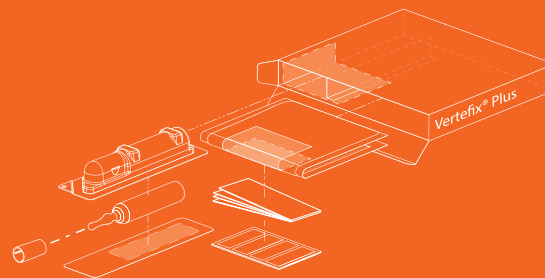
**11G & 13G**

- Vertebroplasty
- Kyphoplasty

### INDICATIONS

- Painful vertebral compression fractures, benign lesions (hemangioma)
- Malignant lesions (Metastatic cancer, myeloma, tumors)
- Treatment of acute & chronic instabilities
- Deformaties of the thoracic, lumbar and sacral spine
- Osteoporosis, osteopenia, metastatic disease

Loaded with **hydroxyapatite** for biocompatibility. The **good radiopacity** enables efficient **visualisation guidance**



### ORDER INFORMATION

## Vertefix® Plus

SET ORDER NUMBER	MIXED VOLUME	CEMENT RADIOPACTY	MAX TEMPERATURE	VISCOSITY	GLOBAL PRODUCT NUMBER
VBC-100-PL	16cc	35%	59° C / 138.3° F	Low	G90002

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# Osteofix®

## Low Exothermic Bone Cement

Used for fixation of pathological fractures of the vertebral body using vertebroplasty and kyphoplasty procedures.

- Two components (powder & liquid) PMMA bone cement
- Cement components are easy to mix, no measurement is required
- Injection time: 15.5 minutes. Yield: 16 cc of PMMA

Supplied sterile in box. Intended for one-time use.



### DELIVERY TECHNIQUE

**Osteo-Site® Needle**

### SIZE

**11G**

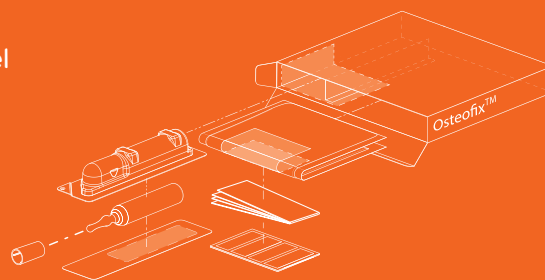
- Vertebroplasty
- Kyphoplasty

### INDICATIONS

- Painful vertebral compression fractures, benign lesions (hemangioma)
- Malignant lesions (Metastatic cancer, myeloma, tumors)
- Treatment of acute & chronic instabilities
- Deformaties of the thoracic, lumbar and sacral spine
- Osteoporosis, osteopenia, metastatic disease

Medium viscosity enables **long working time** and gives the possibility of **multi-level injection procedures**.

The **high rate** of radio-pacifer provides good **visualisation guidance**



### ORDER INFORMATION

### Osteofix®

SET ORDER NUMBER	MIXED VOLUME	CEMENT RADIOCAPACITY	MAX TEMPERATURE	VISCOSITY	GLOBAL PRODUCT NUMBER
VBC-200	16cc	45%	40° C / 104° F	Medium	G90000

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Osteo-Site® Products / Cements

# Thermalfix®

## High Exothermic Bone Cement

Used for fixation of pathological fractures of the vertebral body using vertebroplasty and kyphoplasty procedures.

- Two components (powder & liquid) PMMA bone cement
- Cement components are easy to mix, no measurement is required
- Injection time: 9.5 minutes. Yield: 16 cc of PMMA

Supplied sterile in box. Intended for one-time use.

### DELIVERY TECHNIQUE

**Osteo-Site® Needle**

### SIZE

**11G & 13G**

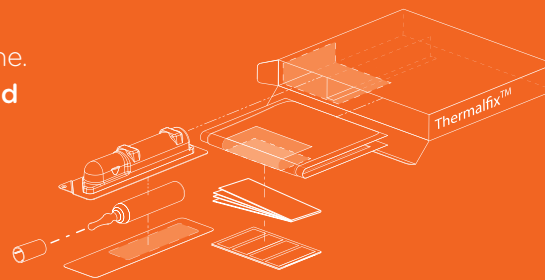
- Vertebroplasty
- Kyphoplasty

### INDICATIONS

- Painful vertebral compression fractures, benign lesions (hemangioma)
- Malignant lesions (Spinal metastases, myeloma)



**Exothermic** bone cement, heat release **exceeding 85° C** when in contact with bone. Radiopacifier of 50% enables **maximum and safe radiological control**



### ORDER INFORMATION

## Thermalfix®

SET ORDER NUMBER	MIXED VOLUME	CEMENT RADIOCAPACITY	MAX TEMPERATURE	VISCOSITY	GLOBAL PRODUCT NUMBER
VBC-300	16cc	50%	88° C / 190.4° F	Low	G90001

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Osteo-Site® Products / Cement Mixers

# Minimix

## Bone Cement Mixer - 4 Ports

Used for mixing bone cement of low and medium viscosity. Closed mixing and loading system enabling sealed transfer of bone cement into syringes.



- Funnel
- 3 end caps
- Spatula
- 2 plastic caps for breaking liquid polymer

Supplied sterile in peel-open packages. Intended for one-time use only.

### FEATURES & BENEFITS

- Mixing paddle design combines powder and liquid components faster and more thoroughly
- Closed system mixer reduces exposure to cement fumes
- Small, compact design allows closed mixing while reducing storage space and waste concerns
- 4 port pressfit connectors

**Simplify** your cement mixing procedure and **reduce fumes** with this compact, **closed system**

### ORDER INFORMATION

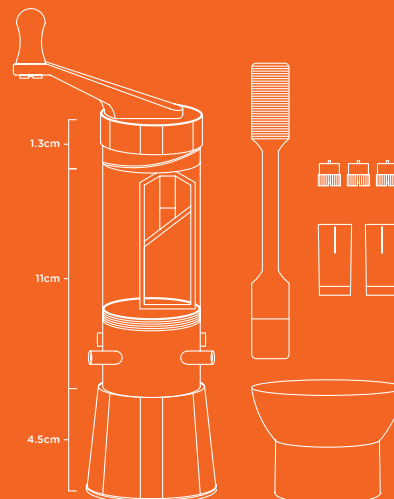
#### Minimix

SET ORDER NUMBER

GLOBAL PRODUCT NUMBER

CMM4

G37374



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Osteo-Site® Products / Cement Mixers

# Minimix

## Bone Cement Mixer - 1 Port

Used for mixing bone cement of low and medium viscosity. Closed mixing and loading system enabling sealed transfer of bone cement into syringes.



- Funnel
- 1 plunger
- Spatula
- 1 Rotating Luer lock adapter

Supplied sterile in peel-open packages. Intended for one-time use only.

### FEATURES & BENEFITS

- Mixing paddle design combines powder and liquid components faster and more thoroughly
- Closed system mixer reduces exposure to cement fumes
- Small, compact design allows closed mixing while reducing storage space and waste concerns

**Simplify** your cement mixing procedure and **reduce fumes** with this compact, **closed system**

**Threaded plunger** provides **control** when moving cement from **mixer to syringe**

### ORDER INFORMATION

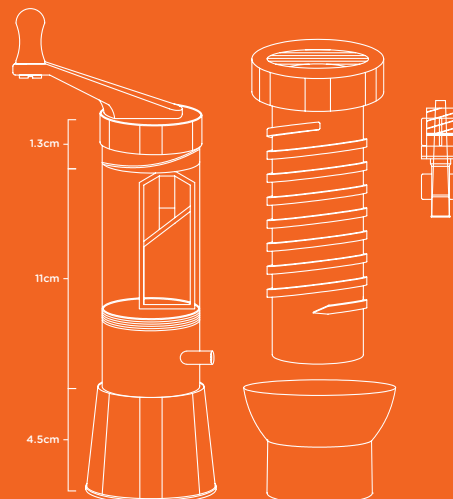
#### Minimix

SET ORDER  
NUMBER

GLOBAL PRODUCT  
NUMBER

CMM1

G90004



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Osteo-Site® Products / Cement Injectors

# Duro-Ject®

## Bone Cement Injector Set

Used for injection of low and medium viscosity bone cement into surgical sites.

Set includes:

- 2 rotating Luer Lock connectors proving free rotational movement of the injector

Supplied sterile in peel-open packages. Intended for one-time use only.



### FEATURES & BENEFITS

- Injector incorporates an ergonomic design, allowing uncomplicated operation
- Injector is supplied with two 10ml injector barrels that are graduated for easy monitoring of low and medium viscosity cement flow
- Set is supplied with two 29cm precurved connecting tubes and two cement funnels for easy loading
- Precision-ground metal threads improve accuracy and control of cement injection
- Each full rotation of injector handle delivers 0.2 ml of cement

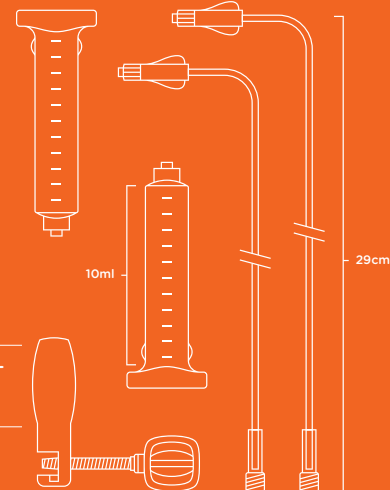
Enhance your **procedural control** with the **ergonomically robust injector** for **low and medium viscosity** cement.

The included 29cm connecting tube **reduces your radiation exposure**. 1 set extra is included for a bipedicular approach

### ORDER INFORMATION

#### Duro-Ject®

SET ORDER NUMBER	SYRINGE VOLUME	CONNECTING TUBE LENGTH	CONNECTING TUBE VOLUME	GLOBAL PRODUCT NUMBER
DURO-100	10ml	29cm	1.4ml	G32497



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Osteo-Site® Products / Cement Injectors

# Osteo-Force®

## Bone Cement Injector Set

Used for injection of low viscosity bone cement into surgical sites



Supplied sterile in peel-open packages. Intended for one-time use only.

### FEATURES & BENEFITS

- Injector has an easy-to-control handle for uncomplicated two-handed operation
- Barrel of syringe holds up to 10 ml of cement
- Syringe incorporates selfpurging technology that evacuates air from the system prior to use
- Supplied with a 15 cm connecting tube
- Each half-rotation of injector handle delivers 0.2 ml of cement

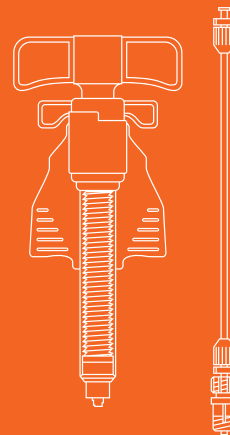
**Reduce** procedure **time** and **costs** with a lightweight, **easy-to-use** injector.

The selfpurging **injector system** is for **low viscosity** bone cement

### ORDER INFORMATION

#### Osteo-force®

SET ORDER NUMBER	SYRINGE VOLUME	CONNECTING TUBE LENGTH	CONNECTING TUBE VOLUME	GLOBAL PRODUCT NUMBER
HPIS-100	10ml	15cm	0.8ml	G13082



Not all parts numbers shown may be approved for sale in all regulatory jurisdictions. Parts and configurations are subject to change without notification. Please consult with your Account Representative for details.

## References

1. Internal files 2. CIRSE Guidelines on Percutaneous Vertebral Augmentation, Georgia Tsoumakidou, Chow Wei Too, Guillaume Koch, Jean Caudrelier, Roberto Luigi Cazzato, 342. 3. International Julien Garnon, Afshin Gangi, Cardiovasc Intervent Radiol (2017) 40:331-342. International Osteoporosis Foundation, 4. The clinical impact of vertebral fractures: quality of life in women with osteoporosis, *Gold DT, Bone* 1996 Mar;18(3 Suppl):185S-189S, 5. Reginster YN, Burlet N. Osteoporosis: a still increasing prevalence, *Bone* 2006;38:S4-S9.

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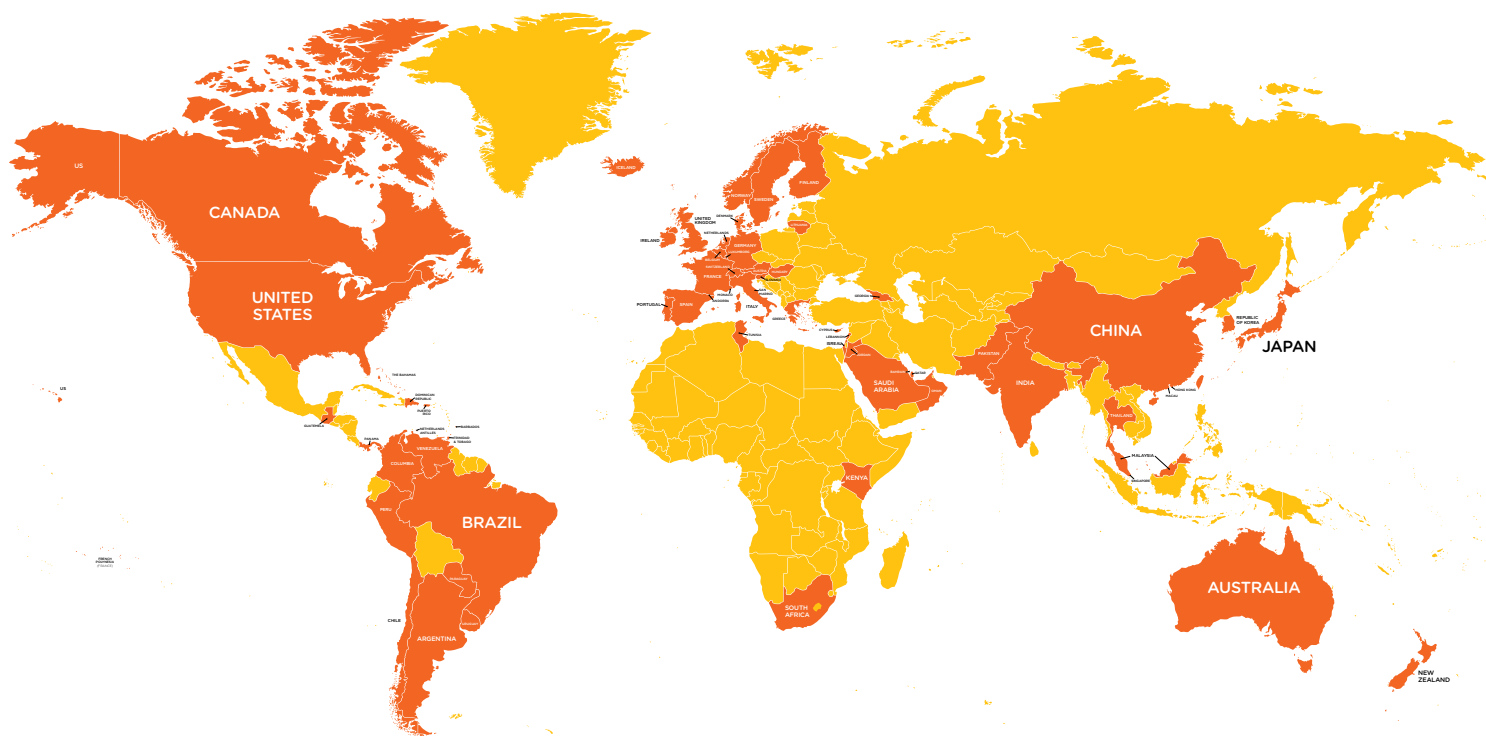
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