



# **MEDINAUT**

Kyphoplasty system & Vertebroplasty system

## Claims for Clinical Performance

### a. Balloon Catheter

- Maximum inflation pressure is 350 psi.
- Initial length of balloon is 10mm(IBE-10, IBEC-10), 15mm(IBE-15, IBEC-15), 20mm (IBE-20, IBEC-20)
- Maximum inflated volume is 3cc(IBE-10, IBEC-10), 5cc(IBE-15, IBEC-15), 7cc(IBE-20, IBEC-20)
- Inflated width of balloon is 14mm(IBE-10, IBEC-10), 17mm(IBE-15, IBEC-15), 19mm (IBE-20, IBEC-20)
- Inflated length of balloon is 16mm(IBE-10, IBEC-10), 22mm(IBE-15, IBEC-15), 34mm (IBE-20, IBEC-20)
- Catheter can be recognized by C-arm or other X-ray facilities.

### b. Inflatable Bone Expander Syringe

- Operating range : 0 to 350 psi
- Accuracy :  $\pm 10\%$  of full scale

### c. ICD Kit

## Contraindication

- 1) Bleeding disorder or treatment that increases the chance of excessive bleeding.
- 2) In the presence of active or incompletely treated infection at the site where the bone cement is to be applied.
- 3) Any known severe allergy to contrast media and bone cements.
- 4) Should not be used if vertebral dimensions or fracture pattern do not allow safe placement and inflation of the balloon.
- 5) If the patient has a confirmed pregnancy.
- 6) Instability of posterior wall and/or pedicles

## Adverse events/ complications

Adverse events potentially associated with use of the Balloon Catheter include:

- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism of other clinical sequelae.
- Rupture with fragmentation of the inflatable portion of the Balloon Catheter resulting in retention of a fragment within the vertebral body.
- Rupture of the Balloon Catheter causing contrast medium exposure, possibly resulting in an allergic reaction or anaphylaxis.
- Deep or superficial wound infection
- Retropulsed vertebral body bone fragments which may cause injury to the spinal cord or nerve roots resulting in radiculopathy, paresis or paralysis.
- Bleeding or hematoma.
  - No fracture or crack when it is bent with radius of 90 degree

## BALLOON CATHETER

MEDINAUT™-X (IBE System) Balloon Catheter is a special product for use of Balloon Kyphoplasty. This system is used with MEDINAUT™-X (IBE System) Inflatable Bone expander syringe for treating vertebral compression fractures due to osteoporosis and cancer.

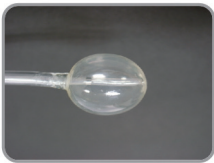
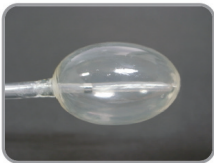
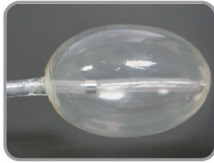
MEDINAUT™-X (IBE System) Balloon Catheter is intended to be used as conventional bone tamps for the reduction of fractures and/or creation of a void in cancellous bone in the spine during balloon Kyphoplasty. MEDINAUT™-X (IBE System) Balloon Catheter is comprised of 3 different lengths-10mm, 15mm and 20mm.

### MEDINAUT™-X (IBE System) Balloon Catheter Features

- Low pre-inflation profile allows for accurate placement inside the vertebral body through cannula.
- Radiopaque markers allow for accurate visualization of balloon while physician positioning balloon prior to inflation with contrast medium.

### Specification and Order Information (Inflation in 37°C)

Order Code	Initial Length(mm)	Max. Inflation Pressure	Max. Inflation Volume(cc)	Inflated Width(mm)	Inflated Length(mm)
IBE-10	10	350	3	14	16
IBE-15	15	350	5	17	22
IBE-20	20	350	7	19	34

Size (Non-actual)		
		
IBE-10	IBE-15	IBE-20



### Key benefits of MEDINAUT™-X (IBE System) Balloon Catheter

- MEDINAUT™-X (IBE SYSTEM) Balloon Catheter has specific design for reducing spinal fractures, create a void and correct vertebral body deformity.
- Inflation of the Balloon Catheter creates a cavity and compacts cancellous bone in the vertebral body for delivering bone cement.

## **INFLATABLE BONE EXPANDER SYRINGE**

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MEDINAUT™ -X (IBE System) Inflatable Bone Expander Syringe by IMEDICOM is a 20ml disposable device with an integral pressure gauge, threaded piston assembly with a handle, a flexible high pressure extension tube, a 20ml locking syringe which is included for transfer of contrast media and a three-way valve for medium pressure.

The syringe is designed to generate and monitor pressures over a range of 0 to 24.6 ATM (0 to 350 PSI).



IMEDICOM's new inflation devices provide reliable and accurate inflation for your demanding cases. Ergonomically designed with accuracy and quality in mind, IMEDICOM inflation devices are available in custom kit configurations.

## INFLATABLE BONE EXPANDER SYRINGE

### Specification and Order Information

Order Code	Operating Range	Accuracy	Liquid Temperature	Humidity Operation Range
IBE-B00	0 ATM (0 PSI) to 24.6 ATM (350 PSI)	±10% of full scale	10 to 40	35% to 65%(RH) Non-condensing humidity



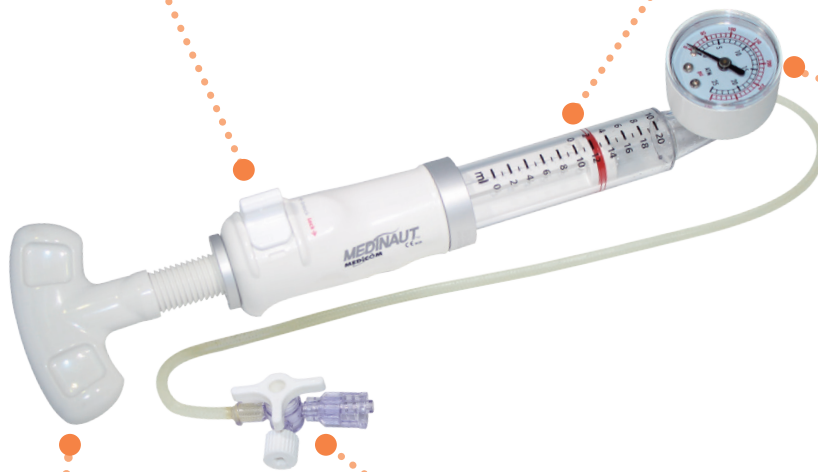
#### Locking Lever

Locking lever is used for change mode to lock or to unlock the handle and piston.



#### Red Indicator

Easily identify current situation with distinct color indicator.



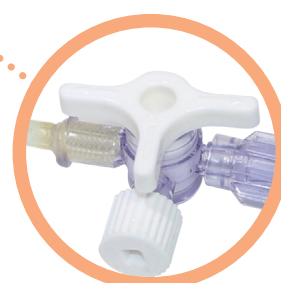
#### Pressure Gauge

Analog pressure gauge helps to indicate current pressure. Max. pressure is 350PSI.



#### Handle

Push or rotate to inflate/deflate the balloon during the operation.



#### 3 Way Valve

Fill contrast Media to Syringe through this valve.

# MEDINAUT™-I

ICD System

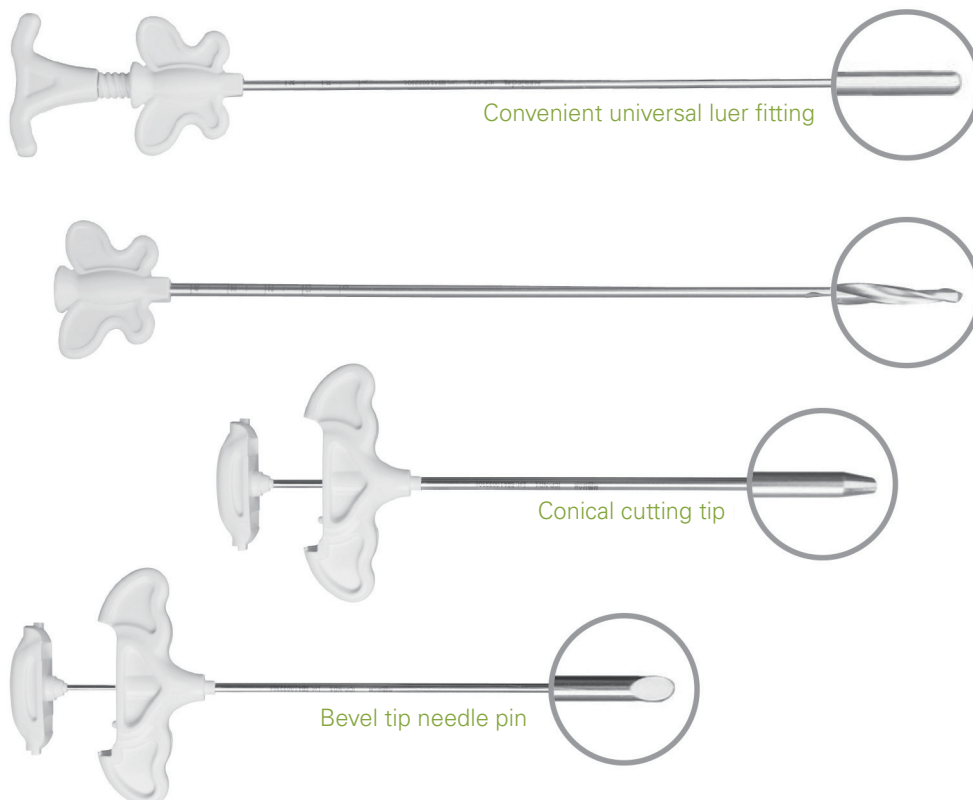
## ICD KIT

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**MEDINAUT™-I (ICD System) ICD Kit by IMEDICOM is intended for percutaneous access to bone and delivery of bone cement.**

- Simple step percutaneous bone access and channel creation-no instrument exchanges
- Available troca and bevel tips for step procedure

**MEDINAUT™-I (ICD System) ICD Kit is comprised of three cement pusher/Filler, one spacer, one cannula, one expander, one needle pin, one needle pipe, one troca type wire-pin, one round type wire-pin and one guide wire(optional).**



MEDINAUT™-I (ICD System) ICD Kit includes an array of well crafted, spine-specific instruments designed for easy access, rapid reduction of spinal fractures and to make of voids in cancellous bone.

MEDINAUT™-I (ICD System) ICD Kit has smaller instruments including single stick access and channel creation for quick and easy access with fewer exchanges.

## ICD KIT

### Specification / Order Code : ICD Kit (Separate order of each unit is not acceptable)



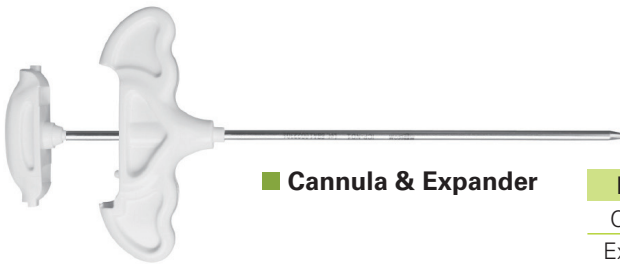
■ **Cement Pusher & Filler (3Set)**

Name	Total Length	Working Length	Diameter	Code
Pusher	253mm	228mm	3.0mm	ICD-CP1
Filler	227mm	187mm	3.5mm	ICD-CF1



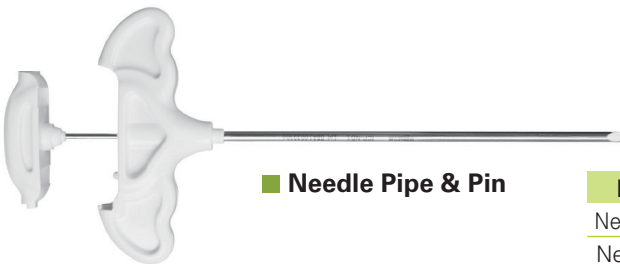
■ **Spacer**

Total Length	Working Length	Diameter	Code
232mm	198mm	3.5mm	ICD-SP1



■ **Cannula & Expander**

Name	Total Length	Working Length	Diameter	Code
Cannula	167.5mm	132mm	4.3mm	ICD-CA1
Expander	175.2mm	159.7mm	3.8mm	ICD-EX1



■ **Needle Pipe & Pin**

Name	Total Length	Working Length	Diameter	Code
Needle pipe	144.8mm	109.5mm	3.0mm	ICD-ND1
Needle pin	152.7mm	136.0mm	1.85mm	ICD-NP1

■ **Wire-Pin Troca Type**

Total Length	Diameter	Code
270mm	1.8mm	ICD-WP2

■ **Wire-Pin Round Type**

Total Length	Diameter	Code
270mm	1.8mm	ICD-WP1

■ **Guide Wire (Optional)**

Total Length	Diameter
308mm	1.1mm



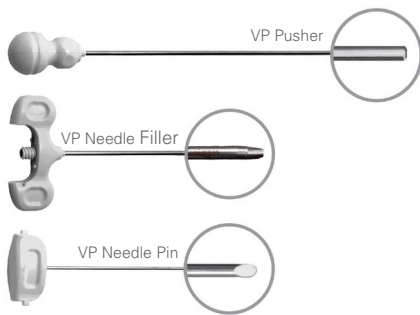
**VERTEBROPLASTY SYSTEM**

**Best Options for Quick Process of Vertebroplasty**

**MEDINAUT™-V (ICD System) IVP Kit by IMEDICOM is intended for percutaneous access to bone and delivery of bone cement.**

- Simple step percutaneous bone access and channel creation-no instrument exchanges
- Available bevel tips for accurate procedure.

MEDINAUT™-V (ICD System) IVP Kit is comprised of one VP needle filler, one VP needle pin and one VP pusher.



MEDINAUT™-V (ICD System) IVP Kit includes an array of well crafted, spine-specific instruments designed for easy access, rapid reduction of spinal fractures and to make of voids in cancellous bone.

MEDINAUT™-V (ICD System) IVP Kit has smaller instruments including single stick access and channel creation for quick and easy access with fewer exchanges.

**Specification and Order Information**

Order Code	Item	Item Code	Total Length	Working Length	Diameter
11G-150	VP Pusher	IVP-PU1	225mm	197mm	2.3mm
	VP Needle Filler	IVP-NF1	183mm	146.7mm	3.0mm
	VP Needle Pin	IVP-NP1	186.3mm	168.5mm	2.3mm
Order Code	Item	Item Code	Total Length	Working Length	Diameter
11G-100	VP Pusher	IVP-PU2	181mm	147mm	2.3mm
	VP Needle Filler	IVP-NF2	133mm	96.7mm	3.0mm
	VP Needle Pin	IVP-NP2	137.3mm	119.5mm	2.3mm
Order Code	Item	Item Code	Total Length	Working Length	Diameter
13G-100	VP Pusher	IVP-PU3	181mm	147mm	1.8mm
	VP Needle Filler	IVP-NF3	133mm	96.7mm	2.4mm
	VP Needle Pin	IVP-NP3	137.3mm	119.5mm	1.8mm
Order Code	Item	Item Code	Total Length	Working Length	Diameter
13G-60	VP Pusher	IVP-PU4	148mm	110mm	1.8mm
	VP Needle Filler	IVP-NF4	93mm	56.7mm	2.4mm
	VP Needle Pin	IVP-NP4	97.3mm	79.5mm	1.8mm

DATE OF ISSUE : CAT-MEDINAUT-00 (REV00, 2014.05.27)