FASTResponder™
Sternal Intraosseous Device

Training Session

Pyng Medical Corp.
Tel: (+1) 604-303-7964

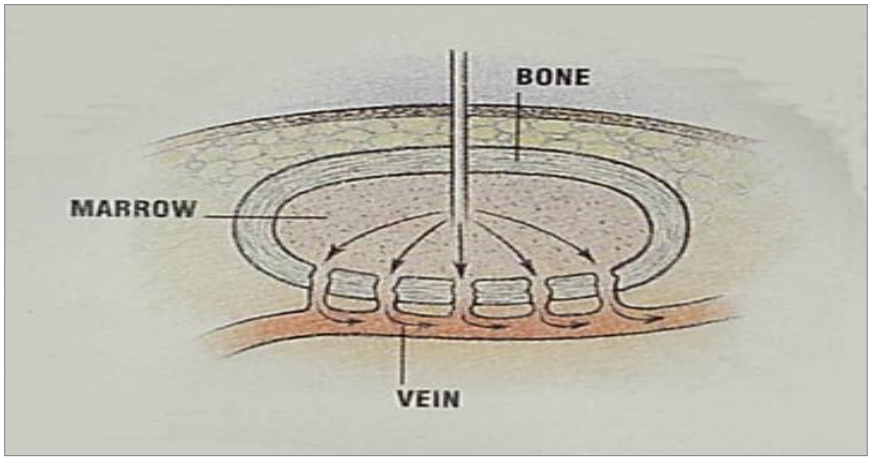
PM-151c

Why IO?

- Peripheral IV is often difficult to obtain[1,2]
- Requires an average of 3-12 minutes[1,2]
- Failure rate ranges between 10-40%[1,2]
- AHA & ILCOR guidelines now recommend IO when IV cannot be obtained

Vascular Access Via IO

- Infuses fluids and medications into bone marrow
- Bone marrow flows into vascular system
- Manubrium especially effective due to close proximity to central circulation



*The **FASTResponder**™ **Sternal Intraosseous Device** is intended for intraosseous infusion as an alternative to IV access to facilitate emergency resuscitation through the use of drugs and fluids.*

Advantages of ***FASTResponder***™

- **FAST**: vascular access within 10 seconds, fluids and medications to the heart in less than 30 seconds
- **SAFE**: automatic depth control prevents over-penetration
- **EFFECTIVE**: can be used as a bridge to a Central Venous Line (CVL) or as a temporary replacement for CVL
- **EFFICIENT**: can be inserted during other resuscitation procedures

MORE Advantages of ***FASTResponder***™

- **MULTI-PURPOSE**: anything that can be given via IV (emergency resuscitation fluids/drugs) can be given via ***FASTResponder***™
- **VERSATILE**: for use in adolescents from 12 years of age and older
- **STERILE**: designed for single, sterile use, no cross-contamination
- **SECURE**: flexible tubing with subcutaneous portal; strain-relief Target Foot ensures line does not become dislodged

MORE Advantages of *FASTResponder*™

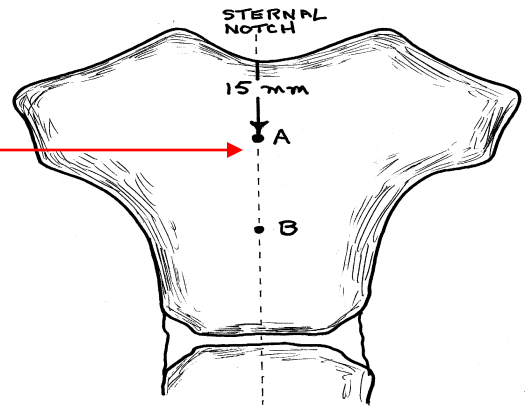
- **ADAPTABLE**: can be inserted in moving ambulances, helicopters and on stretchers
- **QUICK TO LEARN**: skill mastery within minutes
- **EXCELLENT SKILL RETENTION**: ***FASTResponder***™ is easy to learn, difficult to forget

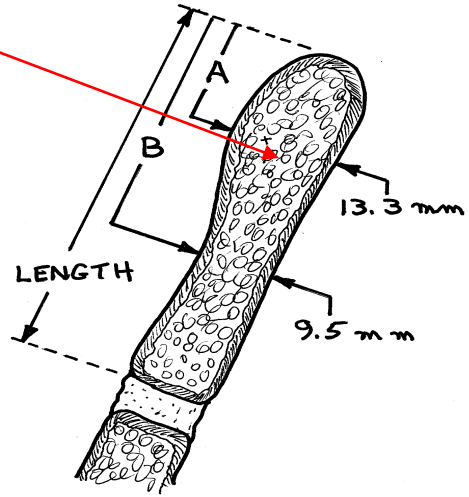
Indications

- For patients 12 years of age and older (adolescent to adult)
- Use whenever vascular access is required to facilitate emergency resuscitation
- Can be left in place up to 24 hours

Insertion Site

- Manubrium of sternum, 15 mm below sternal notch.
- Bone thickness at insertion site:13.30 mm
- Risk of over penetration: less than 1 in 1,000,000

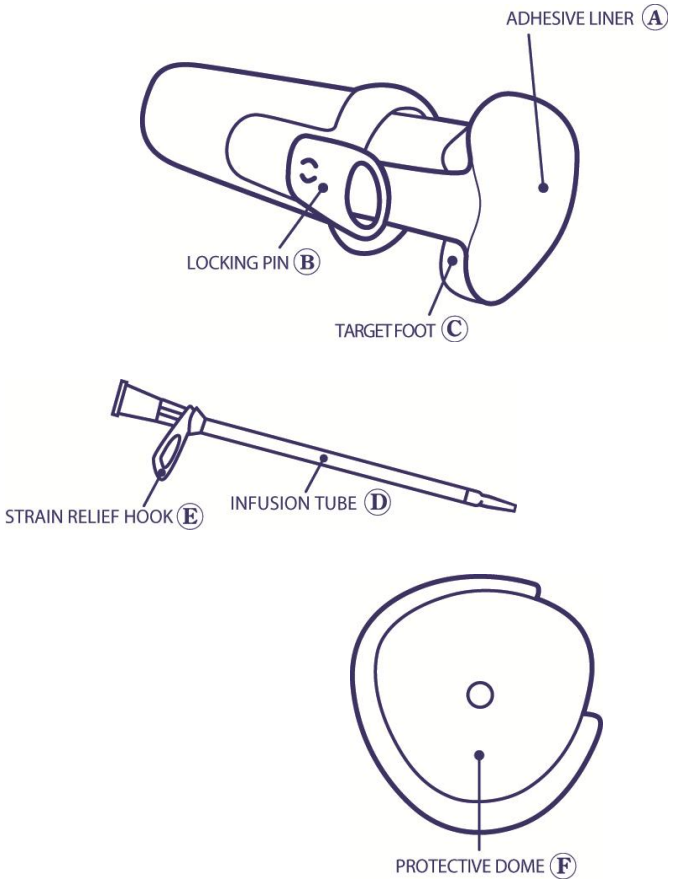




FASTResponder™ Components

FASTResponder™ Explained

- Introducer (device handle assembly) inserts, by user applied force, the Infusion Tube into manubrium
- Infusion Tube is mounted on a stylet inside Introducer
- Bone Probe Needles (not shown) ensures depth control only, they do not penetrate the bone



FASTResponder™ Explained

- Relies on operator force only – it is not spring-loaded, battery dependent, or pneumatic
- Downward force on Introducer pushes steel Infusion Tube tip through soft tissue, into bone
- When steel tip is just inside marrow space, Infusion Tube automatically separates from Introducer
- Bone Probe Needles ensures proper depth control only – they do not enter the bone

FASTResponder™ Explained

- Depth control mechanism prevents over-penetration
- Infusion Tube flexes with movement of patient's skin preventing dislodgements, unlike other IO products which use rigid infusion needles
- Strain-relief mechanism, Target Foot and plastic dome provide additional protection

Insertion
Remember the 6 Ps…

Position (relative to the patient)

Placement (of the device)

Push (to deploy)

Pause (hold target foot)

Pull back (the device)

Prepare (connect fluid source)

FASTResponder™

The Optimal Procedure for Insertion

*This is a precision device, master the insertion procedure for success

SIX STEPS:

Position
Placement
Push
Pause
Pull Back
Prepare

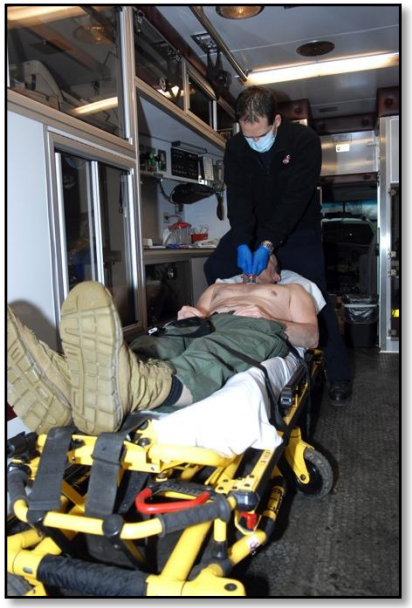
Insertion Procedure

1. Expose sternum and locate the sternal notch

2. Clean insertion site, and dry the skin

Insertion Procedure

3. POSITION: Stand or kneel at head of patient, depending on location and position of patient (optimum position for success)

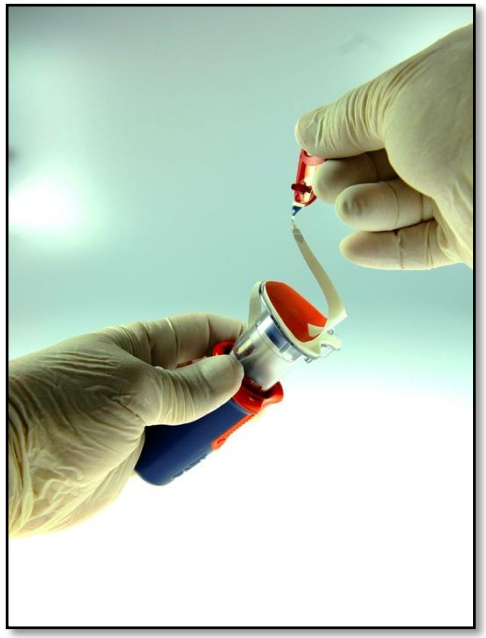


Insertion Procedure

4. Remove the Adhesive Liner with the Locking Pin

#1

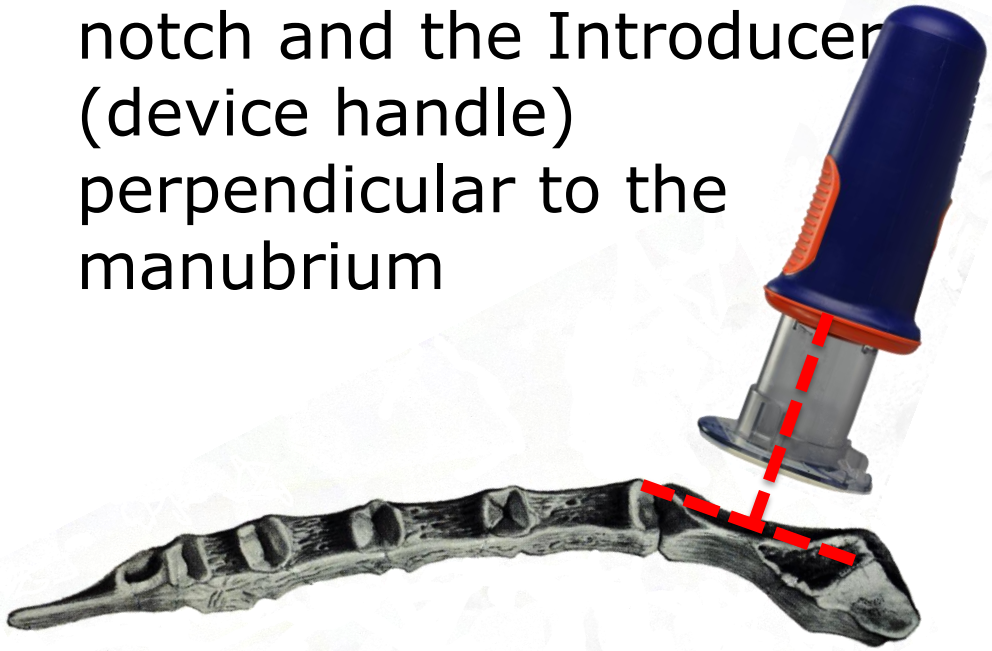
#2

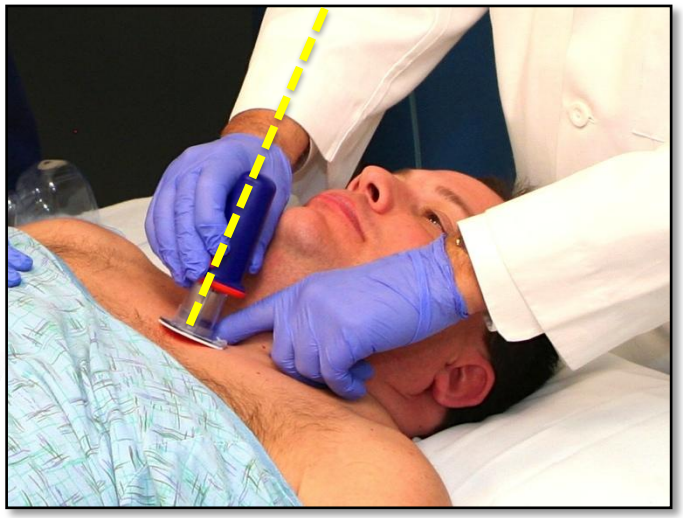


#3

Insertion Procedure

5. PLACEMENT: Align the Target Foot notch with the patient's sternal notch and the Introducer (device handle) perpendicular to the manubrium



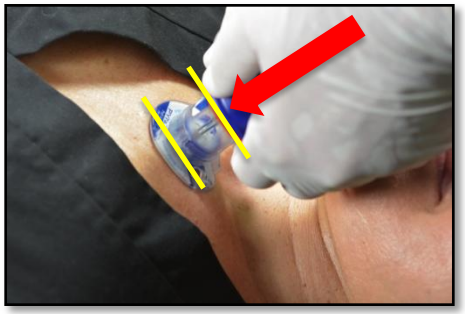


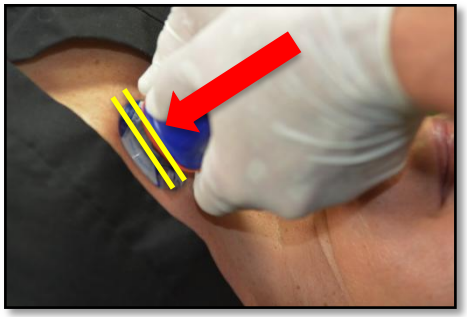
Insertion Procedure

- **CRITICAL**: For safe and effective use of ***FASTResponder™*** verify Target Foot placement at sternal notch.
- **IMPORTANT**: briefly pause the manual CPR procedure or any automatic device like the LUCAS or AUTOPULSE during the short time required for ***FASTResponder™*** deployment in the manubrium.

Insertion Procedure

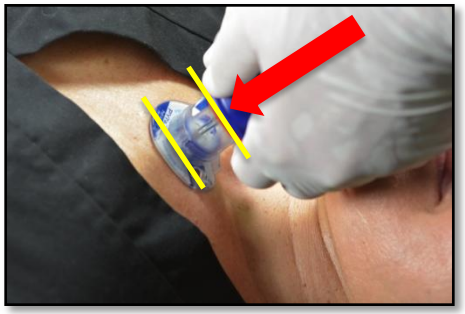
6. PUSH:
FASTResponder™ on axis down completely to the manubrium to deploy the Infusion Tube (optimal if two hands are used as shown)

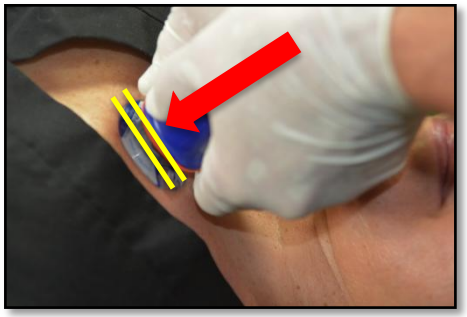




Insertion Procedure

6. PUSH: FASTResponder™ on axis down completely to the manubrium to deploy the Infusion Tube (optimal if two hands are used as shown)

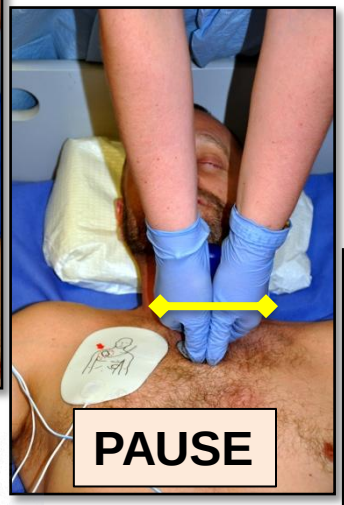


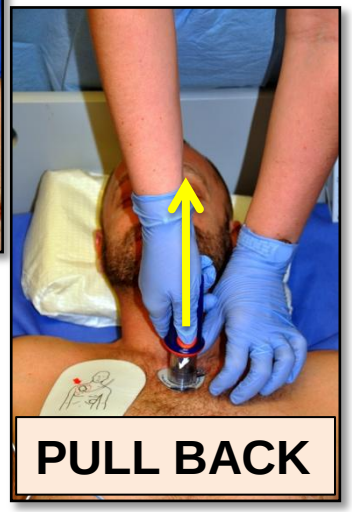


When first deploying FASTResponder there will be more resistance to the insertion than you experienced with Trainers and Simulators. Keep in mind that when deploying FASTResponder you are pushing a metal tip through bone and into the manubrium. The required force must be supplied by you. Bone density and actual resistance will vary from patient to patient.

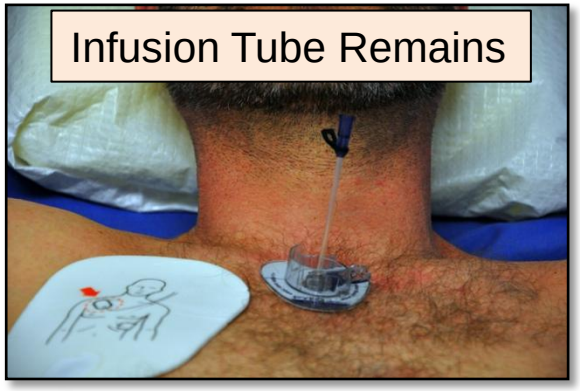
Insertion Procedure

7. PAUSE & PULL BACK: Withdraw FASTResponder™ straight back (on axis) while holding down the Target Foot.





Anti-buckle support comes out with the Infusion Tube (remove & discard)

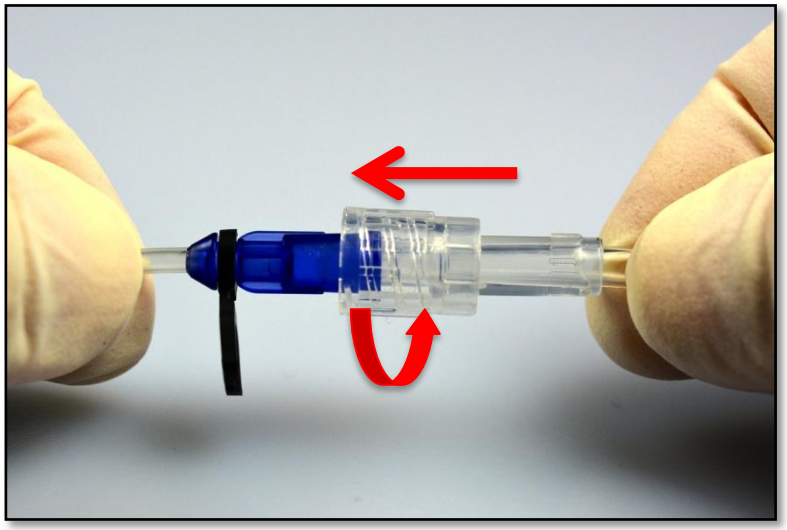


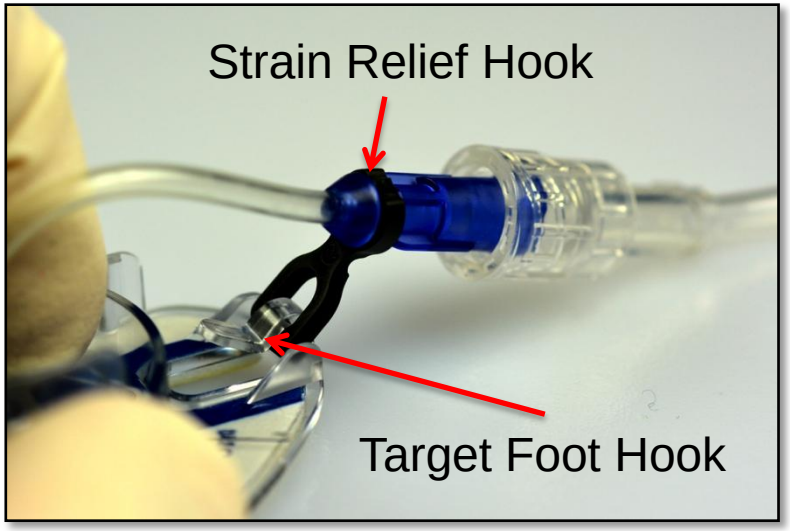
Disposal Procedure

Discard FASTResponder™ device following local contaminated sharps protocols

Insertion Procedure

8. PREPARE: Connect the IV line directly to the luer, and clip the Strain Relief Hook to the Target Foot





Insertion Procedure

9. **Optional** (refer to your protocol):
    - Flush with fluid to clear
    - Confirm placement by aspiration

Optional Procedures

Optional: Remove the liner from the Protective Dome and apply the Dome over the Target Foot infusion site

Optional: (Following medical direction & control) Perform local anesthesia prior to insertion of FASTResponder™

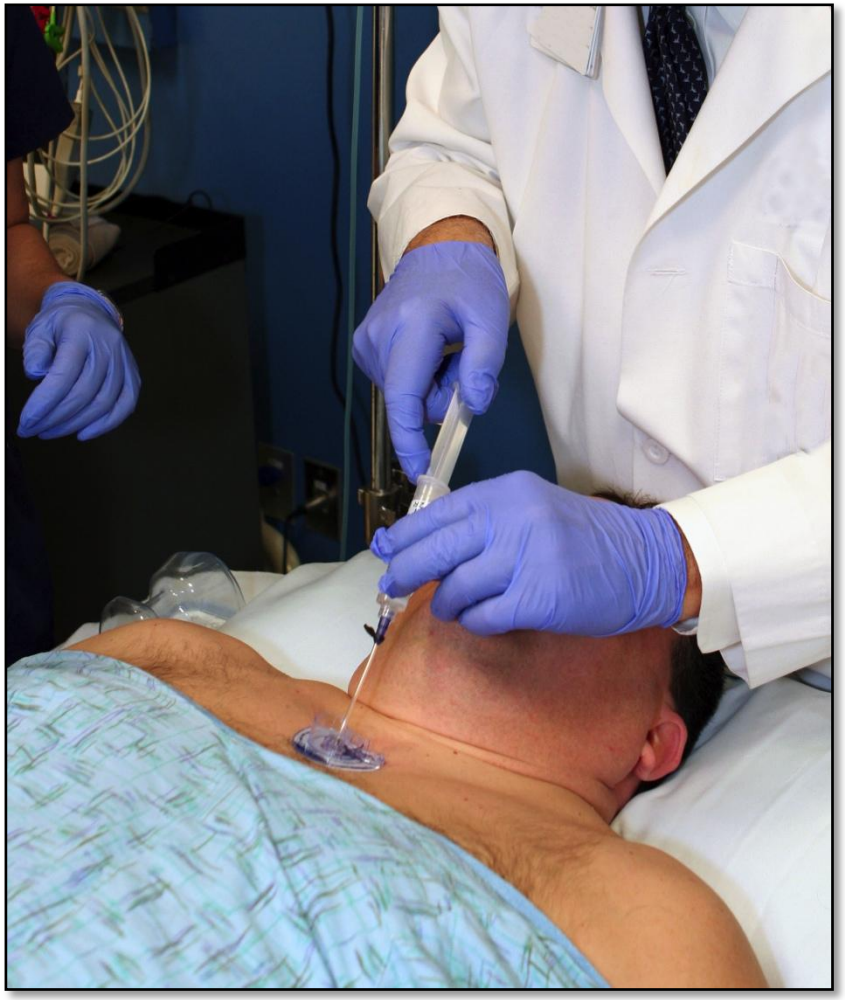
Optional Procedures

Optional: Follow medical direction & control to confirm placement:

1. Attach syringe filled 5cc with normal saline

2. Attach to luer on infusion tube and draw back until marrow is aspirated

3. Push to flush and open infusion tube



Flow Rates

Studies Indicate Fluid Flow Rates[1,3]

- Gravity= 30-80 ml/min
- Pressure infuser= to 120 ml/min
- Syringe= 150-250 ml/min

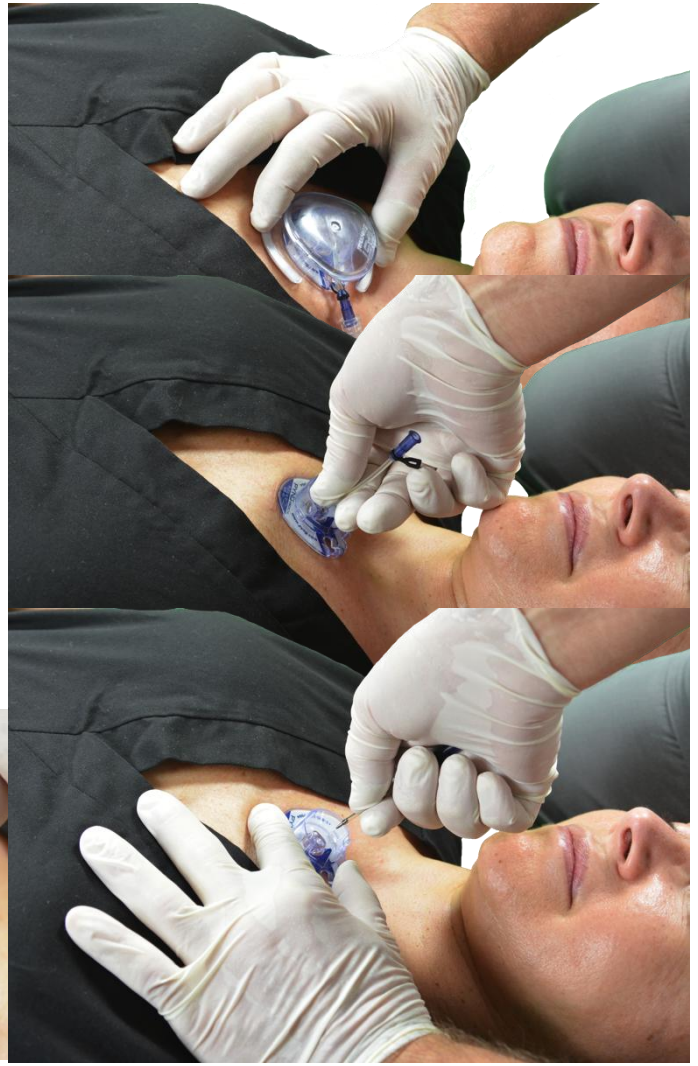
Removal of FASTResponder™

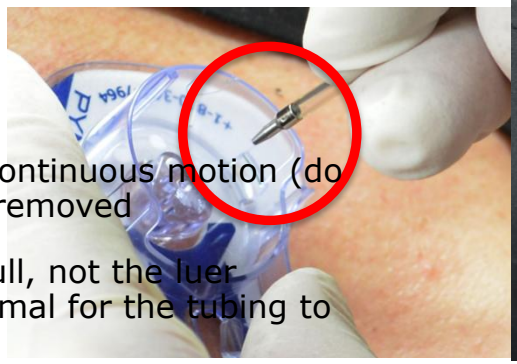
1. Remove Protective Dome from the Target Foot

2. Turn off the source of fluid and disconnect

3. Grasp Infusion Tube with fingers (or clamp) **as close as possible to patient's skin**

4. Pull perpendicular to manubrium until entire Infusion Tube emerges from the patient's chest:





Note:

a. Pull in one quick continuous motion (do not start/stop) until removed

b. Use the tube to pull, not the luer connection. It is normal for the tubing to stretch.

Removal of FASTResponder™

4. Peel off the Target Foot and dress the site as per standard protocol
5. Discard Infusion Tube and Target Foot following local contaminated sharps protocol

Precautions/Warnings

- The function of the device may be affected by trauma, infection, or burns at insertion site
- Safety with very severe osteoporosis has not been proven
- Use in patients with recent sternotomy may prove less effective
- The function of the device may be affected by fracture of the sternum or vascular injury which may compromise the integrity of the manubrium or its vascularization

Precautions/Warnings

- Insertion in sites other than the manubrium may result in ineffective infusion and/or serious injury to the patient and are not approved.
- Reuse of FASTResponder™ is not recommended due to the potential of cross-contamination, which may lead to serious injury or death. FASTResponder™ is unlikely to function after use.

Troubleshooting

Fluid or medication does not flow through IV line to site:

Flush to clear. If fluid or medication does not flow even after flushing, infusion should be discontinued and an alternative method of vascular access should be used.

Leakage at Insertion Site (Extravasation):

If excessive, use alternative method of vascular access.

Troubleshooting

First attempt to place FASTResponder™ fails:

1. Double check insertion site, patient position, medic position, and try again with a new device.
2. Be sure to save the device if the procedure/attempt with FASTResponder™ was not successful (after protecting the sharps) for shipment back to Pyng for examination.

Troubleshooting

Removing entire Infusion Tube (including metal tip):

Pull in one quick continuous motion (do not start/stop) until removed. Use the tube to pull, not the luer connection. It is normal for the tubing to stretch.

Introducer does not release:

Pull Introducer back, if Infusion Tube remains in patient, verify placement by aspirating marrow, proceed with use.

If marrow cannot be withdrawn, remove tube and insert second FASTResponder™.

Troubleshooting

Introducer releases but Infusion Tube is not secured in patient:

Use new FASTResponder™.

Force is applied but Introducer does not release:

Without pulling back, ensure Introducer is perpendicular to manubrium and force is being applied directly along this line.

Troubleshooting

Target Foot and Dome Adhesion:

Cleanse and dry the area of the insertion site prior to deployment. If either the target foot or dome does not adhere to the skin for any reason, medical tape or OPSITE® may be used to provide additional security.

References

1. Macnab, Andrew, Christenson, Jim, Findlay, Judy, Horwood, Bruce, Johnson, David, Jones, Lanny, Phillips, Kelly, Pollack, Charles, Robinson, David J., Rumball, Chris, Stair, Tom, Tiffany, Brian and Whelan, Max : A new system for sternal intraosseous infusion in adults. Prehospital Emergency Care, 4:2, 173-177.

2. Findlay J, Johnson DL, Macnab AJ, MacDonald D, Shellborn R, Susak L: Paramedic evaluation of an adult intraosseous infusion system. Prehospital and Disaster Medicine 2006; 21(5), 329–335.

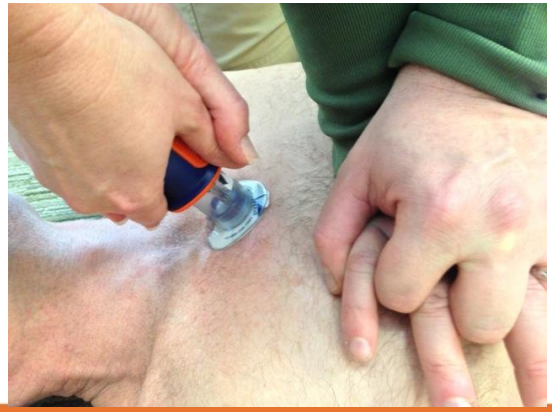
3. David L Johnson; Judy Findlay; Andrew J Macnab; Lark Susak: Cadaver testing to validate design criteria of an adult intraosseous infusion system. Military Medicine, March 2005; 170, 3; ProQuest Medical Library, 251-257.

FASTResponder and CPR

FAST Intraosseous Infusion devices are compatible with all current recommendations and procedures for doing CPR chest compressions.

FAST is placed in the manubrium of the sternum. The manubrium is located at the cephalad (top) portion of the sternum. The hand placement for CPR chest compressions is located just cephalad of the xiphoid process (bottom portion) of the sternum. The position and placement of FAST devices and the hands for chest compressions are separated by the entire body of the sternum.

Deployment of FAST IO can be accomplished while chest compressions are temporarily halted, which takes only a few seconds. Chest compressions (if done correctly) will not affect the placement of the FAST infusion tube. With proper deployment of FAST devices, chest compressions can continue while fluids are administered.



FASTResponder Trainer & Troubleshooting

(11-0080 FASTResponder Training System)

FASTResponder Trainer & Troubleshooting

FASTResponder Trainer consumables / spare parts:

11-0083 FASTResponder Trainer – Box of 5
11-0084 Target Foot Trainer – Box of 10
11-0085 Dome Foam Assembly – Box of 10
11-0086 Reset Rod – Box of 10
11-0087 FASTResponder Trainer Spare Parts

- 10X infusion tube
- 10X antibuckle
- 10X locking pin

FASTResponder Trainer & Troubleshooting

11-0093 Chest-Matt Training Kit for FAST IO

- 1X Chest-Matt model
- 5X Replacement Pucks

11-0094 Chest-Matt Replacement Pucks

- 10X Replacement Pucks

01-0153 SimStern Thin – Box of 50

02-0198 SimStern Marrow – Box of 50

FASTResponder Trainer & Troubleshooting

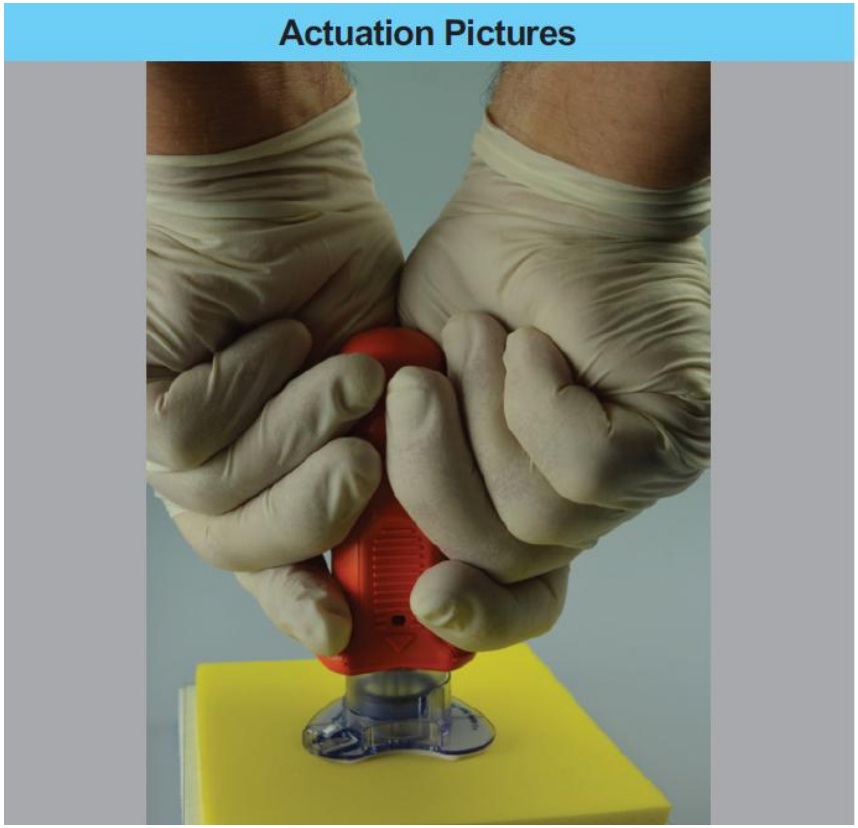
Trainer to be used with SimStern block or Chest-Matt

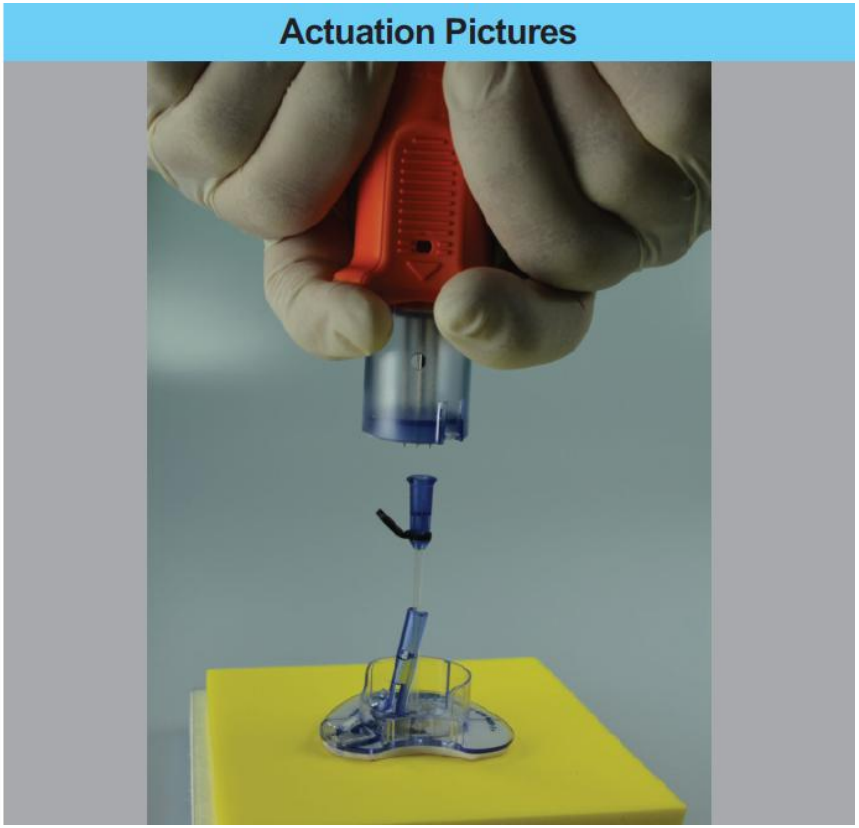
FASTResponder Trainer & Troubleshooting

Device Pictures

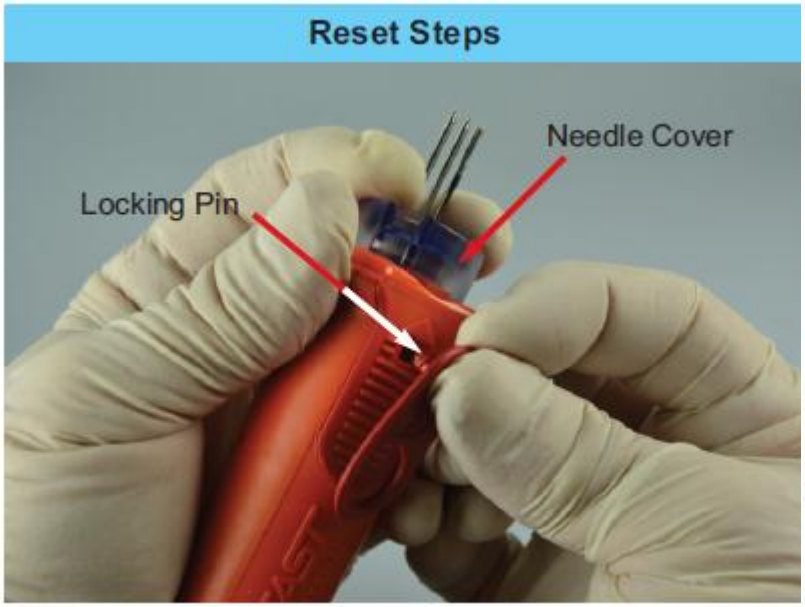
Note: ACTUAL COLOR MAY VARY

FASTResponder Trainer & Troubleshooting





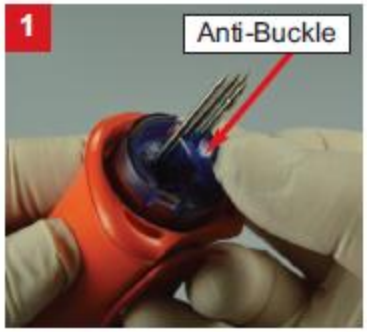
FASTResponder Trainer & Troubleshooting



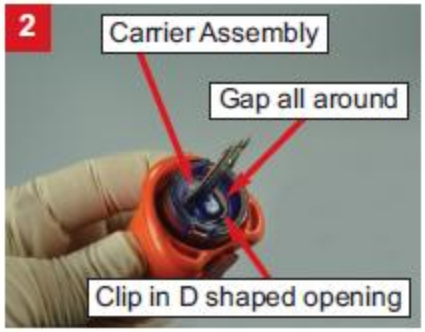
Retract Needle Cover and put Locking Pin in place to hold.

Start to reinstall Infusion Tube on Stylet pin with Strain Relief Hook turned as shown, Srain Relief Hook at "3 O'Clock". Option: it may be easier to reinstall the infusion tube while holding the trainer device horizontally.

FASTResponder Trainer & Troubleshooting



Before completing Infusion-Tube install, replace Anti-Buckle hugging tube. Press and slide the Anti-Buckle along the infusion tube – stylet assembly.



Insert Infusion Tube & Anti-Buckle down making sure clip on Anti-Buckle goes into the "D" shaped opening in the Carrier Assembly & not beside it into the gap.

Holding Needle Cover, remove Locking Pin and **slowly** release Needle Cover up so it does not snap out due to the spring force.

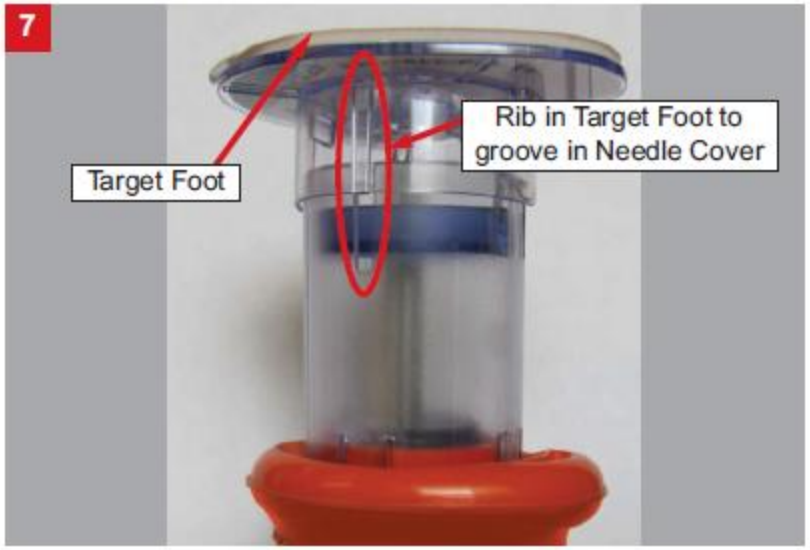
Foot Release Ring flush to end of Needle Cover. Put Locking Pin back in place.

FASTResponder Trainer & Troubleshooting

Using Reset Rod, push Foot Release Ring down from flush (see previous picture) so the Foot Release Ring is at the bottom of slot in Needle Cover.

Remove Reset Rod.

FASTResponder Trainer & Troubleshooting



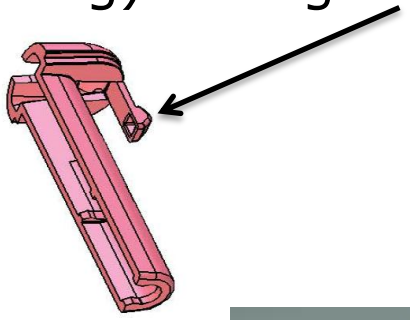
Install Target Foot by lining up rib in Target Foot with groove in Needle Cover.

Replace Locking Pin in orientation shown.
Reset complete.

Note: ACTUAL COLOR MAY VARY

FASTResponder Trainer & Troubleshooting

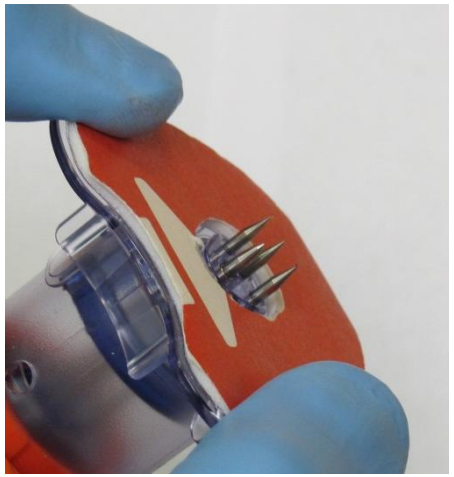
- Antibuckle jam: attempt to remove by pulling out infusion tube, and reseat
- Antibuckle loose (clip bending): realign clip parallel to shaft



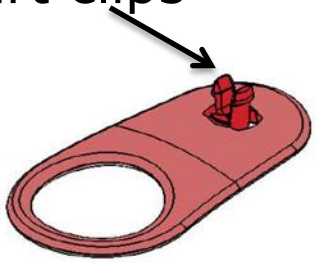
- Blue release ring coming out if needle cover released: insert back in needle cover aligning ramps, push down with reset rod

FASTResponder Trainer & Troubleshooting

- Before each use, check all needles are through target foot holes by slightly pushing down target foot

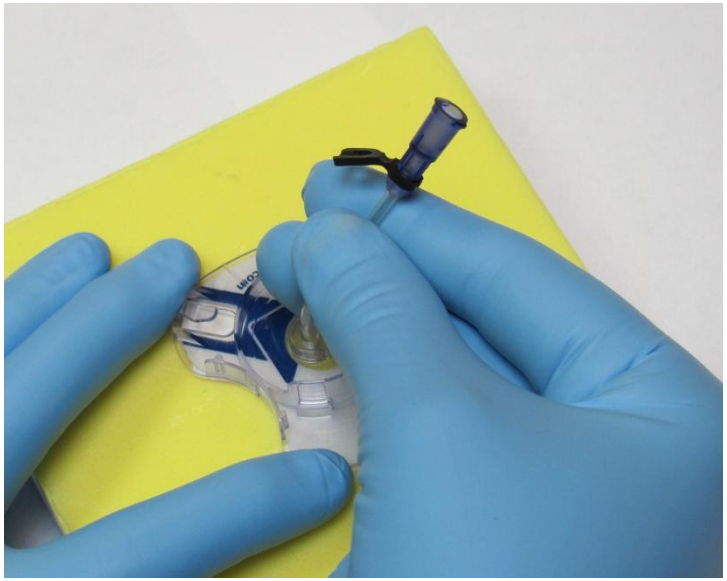


- Locking pin loose: slightly pull apart clips



FASTResponder Trainer & Troubleshooting

- Pulling out tubing to minimize stretching: remove infusion tube by pulling closest to SimStern or Chest-Matt surface



Note: components will wear with re-use and may need to be replaced, spare parts are available