



NEEDLE SETS



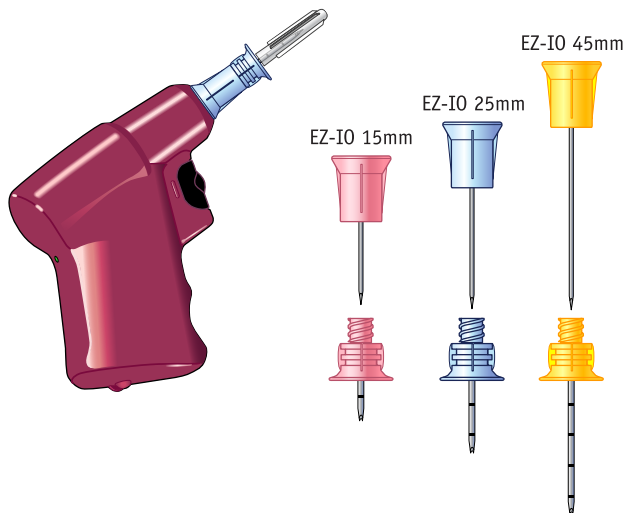
Directions for Use

Immediate Vascular Access...
When You Need It.SM

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1. EZ-IO® 15mm (3-39 KG), EZ-IO® 25mm (40 KG AND GREATER) AND EZ-IO® 45mm (EXCESSIVE TISSUE)

DEVICE DESCRIPTION: EZ-IO Needle Sets are comprised of a Safety Cap, a Stylet and a Catheter. When the Stylet is removed a standard Luer lock is exposed. Needle Sets are made of 304 Stainless and Catheters are 15 gauge. Needle Sets are provided sterile, non pyrogenic and in protective packaging. Needle Sets are intended for use with the EZ-IO Power Driver (Figure 1).



EZ-IO Power Driver and Needle Sets (FIGURE 1)

INDICATIONS FOR USE:**Adults**

For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases.

- Proximal humerus.
- Proximal tibia.
- Distal tibia.

Pediatrics

For intraosseous access with emergent patients where vascular access is difficult.

- Proximal tibia.
- Distal tibia.

Proximal humerus can be used in patients described above when landmarks can clearly be identified.

CONTRAINDICATIONS FOR USE:

- Fracture.
- Excessive tissue and/or absence of adequate anatomical landmarks.
- Infection at the area of insertion.
- Previous, significant orthopedic procedure at the site (IO in past 24 hours, prosthetic limb or joint).

WARNINGS AND PRECAUTIONS:

CAUTION: Use aseptic technique.

CAUTION: Check skin adipose and muscle thickness before insertion (See Figure 1).

CAUTION: 24 hour use only.

CAUTION: Single use only.

CAUTION: Do not recap Needle Sets or separated components.

Use biohazard and sharps disposal precautions.

CAUTION: Stylet and Catheter are **NOT** MRI compatible.

STORAGE: -20°C to 50°C (-4°F to 122°F).

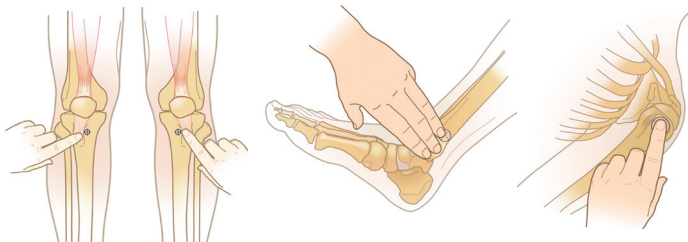


FIGURE 2

INSERTION STEPS:

1. BSI/PPE precautions.
2. Aseptic technique.
3. Locate insertion site. (Figure 2)
4. Prepare insertion site. (Figure 3)
Tibial site shown for clarity.
5. Prepare infusion system.
6. Ensure that the Driver and Needle Set are securely seated. (Figure 4)
7. Remove and discard the Needle Set Safety Cap from the IO Needle Set installed on the EZ-IO Power Driver. (Figure 5)
8. Insert EZ-IO Needle Set.

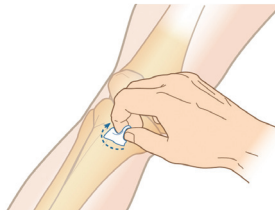


FIGURE 3



FIGURE 4



FIGURE 5

- IMPORTANT:** Only handle Needle Set by the plastic hub.
- IMPORTANT:** Control the patient's movement prior to and during Needle Set insertion.

- a. Position Driver at insertion site with Needle Set at a 90-degree angle to the bone. (Figure 6) **Gently** power or press Needle Set until Needle Set tip touches bone.
- b. Ensure at least 5 mm of the catheter is visible. (Figure 7)

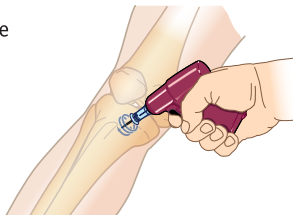


FIGURE 6

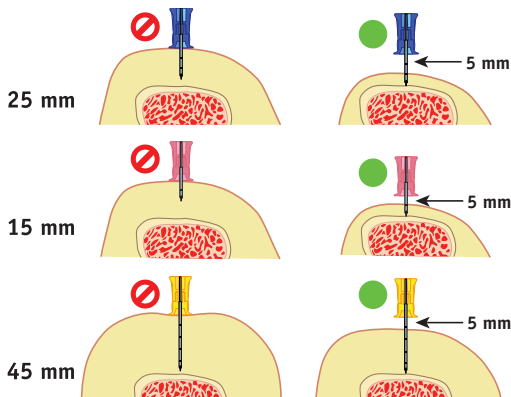


FIGURE 7

- c. Penetrate bone cortex by squeezing the Driver's trigger and applying **gentle, steady downward pressure**.
- d. Release Driver's trigger and stop insertion process when:
 1. A sudden "give" or "pop" is felt upon entry into the medullary space.
 2. The desired depth is obtained.

IMPORTANT:

Use gentle-steady pressure. DO NOT USE EXCESSIVE FORCE. Allow the Needle Set rotation and gentle downward pressure to provide the penetrating action.

Note: *If the Driver stalls and will not penetrate the bone you may be applying too much downward pressure.*

Note: *In the unlikely event of a driver failure, remove the Power Driver, grasp the needle set by hand and advance the needle set into the medullary space while twisting the needle set.*

9. Remove Power Driver and Stylet. (Figure 8)

10. Confirm Catheter stability.

11. Attach EZ-Connect® Extension Set. (Figure 9)

Prior to attaching the EZ-Connect® perform the following steps:

- a. Open Clamp if required.
- b. Attach female adapter to product source.
- c. Prime set and purge air.
- d. Attach male adapter to access device with a firm push and best motion.
- e. Engage the Luer lock collar in order to prevent accidental disconnection.
- f. Continue with procedure for fluid transfer.

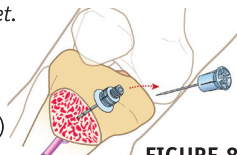


FIGURE 8

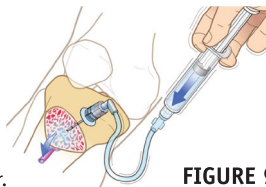


FIGURE 9

DO NOT ATTACH A SYRINGE DIRECTLY TO THE EZ-IO CATHETER HUB EXCEPT WHEN DRAWING BLOOD FOR LABORATORY ANALYSIS, WITH THE NEEDLE SET STABILIZED.

12. Flush the EZ-IO catheter with 10 ml of Normal Saline.

IMPORTANT:

Prior to flush consider the aspiration of a small amount of blood to confirm placement.

- **Consider IO 2% lidocaine without preservatives or epinephrine (cardiac lidocaine) for patients responsive to pain prior to flush. Follow institutional protocols/policy.**
- Medications intended to remain in the medullary space, such as a local anesthetic, must be administered very slowly until the desired anesthetic effect is achieved.
- **NO FLUSH = NO FLOW.** Failure to appropriately flush the EZ-IO catheter may result in limited or no flow. **REPEAT FLUSH AS NEEDED.**
- Once EZ-IO catheter has been flushed, administer fluids or medications as indicated.

Note: *Frequently monitor the insertion site for extravasation.*

13. Apply dressing and EZ-IO wristband.

14. Remove catheter from patient.

Attach Luer lock syringe, continuously rotate clockwise while slowly and gently applying traction to catheter. **DO NOT ROCK OR BEND THE CATHETER DURING REMOVAL.** (Figure 10)

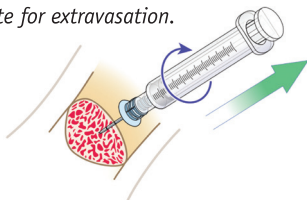


FIGURE 10

Once removed, immediately place catheter in appropriate sharps container.

15. Dress site as appropriate.

CAUTION: Do not leave the catheter inserted for longer than 24 hours.

Education and training materials available at Vidacare.com



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U.S. AND CANADA 24 HOUR TOLL FREE

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R_x CAUTION: Federal (U.S.A.) law
restricts this device to sale by
ONLY or on the order of a physician.

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