



Intraosseous Vascular Access

EZ-IO[®] INTRAOSSEOUS VASCULAR ACCESS NEEDLES



Instructions for Use

Vidacare.com

INDICATIONS FOR USE:

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

ADULTS & PEDIATRICS

- Proximal humerus
- Proximal tibia
- Distal tibia

CONTRAINDICATIONS FOR USE:

- Fracture in target bone.
- Previous, significant orthopedic procedure at the site, prosthetic limb or joint.
- IO in past 48 hours of the target bone.
- Infection at the area of insertion.
- Excessive tissue (severe obesity) and/or inability to clearly identify anatomical landmarks.

WARNINGS AND PRECAUTIONS FOR**EZ-IO[®] INTRAOSSEOUS VASCULAR ACCESS SYSTEM:**

CAUTION: Use aseptic technique.

CAUTION: Check skin, adipose and muscle thickness before insertion.

CAUTION: Extra care should be taken during insertion and site monitoring when used in patients with bone diseases that increase the likelihood of fracture, extravasation and dislodgement.

CAUTION: Do not recap Needle Sets or reconnect separated components. Use biohazard and sharps disposal precautions.

CAUTION: Before administering vesicant, toxic, or highly-concentrated drugs, check the IO Catheter again for placement and patency.

CAUTION: Use caution with chemotherapeutic agents.

CAUTION: Monitor insertion site frequently for extravasation.

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

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

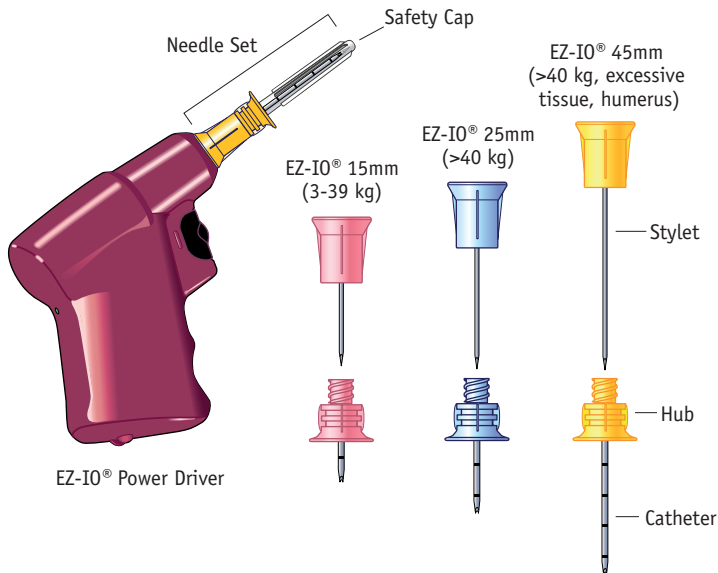
CAUTION: Needle Sets are single use only.

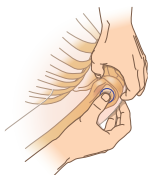
STORAGE: -20°C to 50°C (-4°F to 122°F).

EZ-IO® NEEDLE SETS: DESCRIPTION

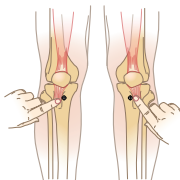
- Comprised of Catheter with Luer-lock connection, Stylet, Safety Cap.
- 15 gauge, 304 stainless steel in 15mm, 25mm and 45mm lengths.
- Sterile, non-pyrogenic, in protective packaging.
- Intended for use with EZ-IO® Power Driver.

EZ-IO® Power Driver and Needle Sets: Description

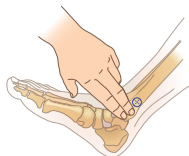




Proximal Humerus



Proximal Tibia



Distal Tibia

1. Clean insertion site per institutional protocol/policy.

2. Prepare supplies.

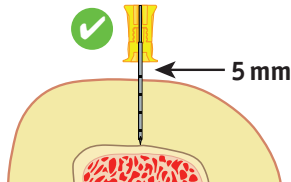
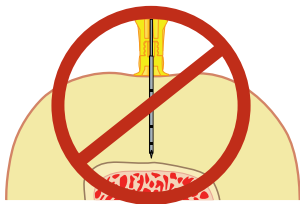
- a. Prime EZ-Connect®.
 - Unlock clamp.
 - Prime set and purge air.
- b. Open EZ-Stabilizer™ package.

3. Attach Needle Set to EZ-IO® Power Driver and remove Safety Cap from Catheter.

IMPORTANT: Only handle Needle Set by the plastic Hub.

IMPORTANT: Control patient movement prior to and during procedure.

4. Push Needle Set through skin until tip touches bone.



5. 5mm of the Catheter (at least one black line) must be visible outside the skin.

6. Squeeze trigger and apply moderate steady pressure.

IMPORTANT: DO NOT USE EXCESSIVE FORCE. Use moderate steady downward pressure and allow Needle Set rotation to penetrate the bone.

Note: If Driver stalls and Needle Set will not penetrate the bone, operator may be applying too much downward pressure to penetrate bone.

Note: In the event of a Driver failure, disconnect the Power Driver, grasp the Needle Set Hub by hand and advance into the medullary space while twisting.

7. Advance Needle Set and release Trigger.

Pediatrics: Release trigger when sudden “give” or “pop” is felt, indicating entry into medullary space.

Adult: Advance Needle Set approximately 1-2cm after entry into medullary space; in Proximal humerus for most adults Needle Set should be advanced 2cm or until Hub is flush or against the skin.

8. Stabilize Needle Set Hub, disconnect Driver, and remove Stylet.

9. Place Stylet into NeedleVISE® for sharps containment.

Note: Place the NeedleVISE® on a flat stable surface. Immediately following use of a Needle and while still holding it with one hand away from the sharp end, firmly insert the sharp pointed tip straight down into the opening in the NeedleVISE® until it stops, making sure to **KEEP YOUR FREE HAND AWAY FROM THE SHARPS SECURING DEVICE DURING INSERTION. DO NOT HOLD NeedleVISE® WITH FREE HAND WHILE INSERTING NEEDLE. ALWAYS USE ONE-HANDED TECHNIQUE WHEN INSERTING SHARP** into NeedleVISE®. Dispose of opened sharp into NeedleVISE® whether or not it has been used.

10. Obtain samples for lab analysis, if needed.

Note: Only attach a Syringe directly to the EZ-IO® Catheter Hub when drawing blood for laboratory analysis (stabilize Catheter) or removal.

11. Use of the EZ-Stabilizer™ is strongly recommended for all EZ-IO® insertions.

a. Place Stabilizer over Catheter Hub.

12. Attach a primed EZ-Connect® extension set to the Hub, firmly secure by twisting clockwise.

Note: Do NOT use any instruments to tighten connections.

Note: To prevent valve damage, Do NOT use needles or blunt cannula to access the swabable valve. Non-standard syringes or connectors can damage the swabable valve.

Note: Operator may use a sterile alcohol wipe, to swab the surface of the EZ-Connect® valve and let it air dry.

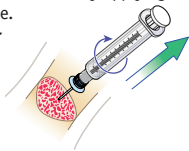
13. Attach EZ-Stabilizer™ dressing by pulling the tabs to expose the adhesive and adhere to skin.
14. For patients responsive to pain, consider 2% preservative and epinephrine free lidocaine (intravenous lidocaine), follow institutional protocols/policy.
 - a. Local anesthetics intended for the medullary space must be administered very slowly until desired anesthetic effect is achieved.
15. Flush the EZ-IO® with normal saline (0.9% Sodium Chloride) (5-10mL for adults; 2-5mL infant/child).
 - a. Prior to flush, aspirate slightly for visual confirmation of bone marrow.
 - b. Failure to appropriately flush the EZ-IO® Catheter may result in limited or no flow. Repeat flush as needed.
 - c. Once EZ-IO® Catheter has been flushed, administer fluids or medications as indicated.
16. Confirm Catheter placement with the following recommended methods:
 - Stability of Catheter in the bone.
 - Ability to aspirate after flush.
 - Adequate flow rate.
17. Document date/time of insertion and apply EZ-IO® wristband.

CAUTION: Monitor insertion site frequently for extravasation.

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

To remove EZ-IO® from patient:

- a. Remove EZ-Connect®.
- b. Lift & remove EZ-Stabilizer® adhesive dressing.
- c. Attach Luer-lock Syringe to Hub of Catheter. Withdraw the Catheter by applying traction while rotating the Syringe and Catheter clockwise. Maintain axial alignment during removal, **do NOT rock or bend the Catheter.**
- d. Once removed, immediately place Syringe/Catheter in appropriate sharps container.
- e. Dress site per institutional protocol/policy.



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At the completion of the EZ-IO® Intraosseous Vascular Access Driver's service life, proper disposal is the responsibility of the institution or service (directive 2012/19/EU).



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



Degree of protection against electric shock BF Applied part.



The EZ-IO® System Conforms to the Medical Device Directive (93/42/EEC)



Consult instructions for use

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