Installing an intraosseous Infusion System (EZ-IO®)

(See annex "Direction for Use" by Vidacare for a quick guide or watch the video in the bibliography for more details)

IMPORTANT: This protocol is intended for emergency use requiring a vascular access. All nursing and medical professionals that have obtained training/demonstration on the installation of EZ-IO may proceed with the technique after approval by consulting physician **OR** nurses without training may proceed only with the guidance of the physician and the procedures contained in this guide.

The EZ-IO[®] Intraosseous Infusion System is a complete solution for immediate vascular access — whether you're facing difficult vascular access challenges or need immediate intraosseous access for critical situations and life-threatening emergencies. EZ-IO provides rapid, smooth entry into the bone's medullary cavity, creating an immediate conduit to the central circulation.

- All IV fluids or IV medications can be administered via an IO (including pressors and blood products).
- Doses of medications are the same as per IV administration.
- Infusion rate achieved with a pressure pump or syringe will be similar to a 21G peripheral line. IO medication administration is as efficient as per a central line.
- IO is a temporary access, and is not to be used for more than 24 hours.

INDICATIONS OF USE

- All adult and pediatric patients who need vascular access in emergent, urgent or medically required cases and for whom a peripheral line is not easily accessible
- Have an immediate need for medications or fluids
- Require multiple IV sticks to obtain vascular access for medication or fluid infusion
- Need urgent fluid resuscitation
- Are in cardiac or respiratory arrest
- Require rapid intubation or sedation
- Intraosseous access for emergencies

CONTRAINDICATIONS OF USE

Use an alternate site if possible and if presence of any conditions below:

- Fracture of the bone selected for IO infusion
- Absence of anatomical landmarks (for example: due to excessive tissue or swelling)
- Previous significant orthopedic surgery of the nearest joint (e.g. knee prosthesis)
- IO insertion within the past 24 hours on the same bone
- Infection at site of IO insertion
- NB: hemophilia or coagulopathy is *not* a contra-indication

PREPARATION MATERIALS

- EZ-IO Power Driver
- Appropriate size intraosseous Needle Set based on patient size and weight
- EZ-IO 15mm pink: pediatrics 3-39 kg
- EZ-IO 25mm blue: adults >40kg
- EZ-IO 45mm yellow: adults >40kg with excessive tissue
- 1 EZ-Connect
- 2 x 10 ml syringes
- Sterile saline solution for flush

- Consider 2% lidocaine (without preservatives and without epinephrine, i.e. cardiac lidocaine) for patients responding to pain
- Non-sterile non-latex gloves, protective mask and glasses
- Antiseptic agent (example lodine or Chlorhexidine)
- One (1) semi-permeable transparent dressing (optional)
- One (1) sterile 2x2 or 4x4 gauze pad
- One (1) (appropriate volume and type) intravenous solution
- One (1) fluid administration set
- One (1) fluid administration pump or pressure bag if available or syringe
- EZ-Stabilizer

INSERTION SITES

Refer to images provided in the annex for "Direction of Use":

Age	IO sites (by order of preference)	Comments on insertion site
<1 year old	1- Proximal tibia 2- Distal femur	Prox Tibia: 2 cm below tibial tuberosity and up to 1 cm medially on the tibial plateau Femur: midline approximately 1 to 2 cm above the superior border of the patella with the leg in extension
1 – 18 year old	1- Proximal tibia 2- Distal tibia or fibula	Prox tibia: 2 cm below tibial tuberosity and up to 1 cm medially on the tibial plateau Malleoli: 1 to 2 cm superior to the malleoli in the midline (medial malleola is preferred)
>18 year old (mature skeleton)	1- Proximal tibia 2- Proximal humerus (use 45mm needle set) 3- Distal tibia or fibula	Proximal tibia: 2 cm medial and 1 cm above the tibial tuberosity Humerus: adduct and internally rotate the upper arm (hand on abdomen) The greater tubercle of the proximal humerus is located 2 cm below the acromion process, or, it can be directly palpated from below Malleoli: 1 to 2 cm superior to the malleoli in the midline (medial malleola is preferred)

PROCEDURE

If the patient is conscious, first explain the procedure

- Apply non-sterile latex free gloves; wear protective mask and glasses
- Cleanse site using antiseptic agent and allow to air dry
- Consider local anesthesia if patient is alert (example: 1-2 ml xylocaine 1% with or without epinephrine injected subcutaneously)
- Connect appropriate Needle Set to power driver
- Stabilize site
- Remove needle safety cap
- Keep hand and fingers away from Needle Set
- Position the driver at the insertion site with the needle set at a 90-degree angle to the bone surface.
- Gently pierce the skin with the Needle Set until the Needle Set tip touches the bone (do not activate power driver yet).

- Ensure there is still visualization of at least one black line on the needle
- Penetrate the bone cortex by squeezing driver's trigger and applying gentle, consistent, steady, downward pressure (allow the driver to do the work)

*Do not use excessive force. In some patients insertion may take greater than 10 seconds, if the driver sounds like it is slowing down during insertion; reduce pressure on the driver to allow the RPMs of the needle tip to do the work.

*In the unlikely event that the battery on the Driver fails, clinicians may manually finish inserting the EZ-IO Needle Set. Grasp the Needle Set and rotate your arm, while pushing the needle into the intraosseous space. This may take several minutes.

- On adult patients when accessing the tibia using the 25mm Needle Set or the proximal humerus
 using the 45mm Needle Set, you may stop by releasing the trigger when the hub is almost flush
 with the skin.
- On pediatric patients when you feel a decrease in resistance indicating the Needle Set has entered the medullary space, release (stop pushing) the trigger.
- Remove EZ-IO Power Driver from Needle Set while stabilizing the catheter hub
- Remove stylet from catheter by turning counter-clockwise and immediately dispose of stylet in appropriate biohazard sharps container
- Secure site with EZ Stabilizer
- Consider withdrawing blood for **diagnostic studies** (notify lab that they are from an IO source):
 - These values are reliable if blood samples are taken during initial installation of IO: Glucose, hemoglobin, pH, pCO2, serum bicarbonate, sodium, chloride, blood urea nitrogen, creatinine, serum drug levels, cultures (bacterial, viral, or fungal), ABO and Rh type for type and screen.
 - These values may not be accurate: Blood oxygenation, white blood cell count, potassium, AST, ALT, ionized calcium.
- Connect pre-primed EZ Connect (example: with Normal Saline) to exposed Luer-lock hub
- If the patient is responsive to pain, consider administration of anesthetic via the IO catheter: slow administration over 1 minute of preservative-free/epinephrine-free 2% lidocaine (ie use cardiac lidocaine found in crash cart not the lidocaine used for local anesthesia):
 - o Dose: 0.5 mg/kg (20 mg/mL); max dose: 40 mg (2ml)
 - o weight examples: 20kg: 10mg (0.5ml); 80kg: 40mg (2ml)
- **Syringe 10ml bolus**: flush the catheter with a rapid and vigorous 10 ml flush of normal saline prior to infusions; repeat this flush as needed if flow still not adequate. "**NO FLUSH = NO FLOW**"
- Assess for potential IO complications and infiltration
- Disconnect 10 ml syringe from EZ-Connect extension set
- Connect primed EZ-Connect extension set to primed IV tubing
- Begin infusion utilizing a pressure delivery system (infusion pump, pressure bag at 300mmHg (if available), or simply using a large syringe and manually pushing fluids and medications)
- Secure tubing; cover the IO site with gauze pad and dry dressing
- Continue to monitor extremity for complications or infiltrations
- Document time and date of EZ-IO insertion (VERY IMPORTANT: IO CANNOT BE USED FOR MORE THAN 24 HOURS)
- IO site should be flushed before and after each medication administration.

PROCEDURE ON HOW TO REMOVE AN IO

- Explain the procedure to the patient if alert
- Remove EZ Connect IV tubing

- Secure an empty 10cc syringe directly onto the IO needle
- Apply continuous gentle traction while turning the syringe and IO needle clockwise until the needle is removed; discard of needle appropriately
- Apply pressure onto wound site and apply a simple dry dressing. No need for prolonged pressure or pressure dressing unless clinically indicated.

PRECAUTIONS

- Do not leave IO catheter inserted for more than 24 hours
- Use aseptic technique
- Check skin adipose and muscle thickness before insertion
- Single use only
- Do not recap Needle Sets
- Stylet and catheter are **NOT** Magnetic Resonance Imaging (MRI) compatible

CLINICAL FOLLOW-UP

- Frequently assess for potential IO complications such as extravasation and infiltration, tibial fracture, osteomyelitis, epiphyseal injury, hemorrhage, fat embolism, low extremity compartment syndrome, obstruction of needle with marrow, bone fragments, or tissue, skin necrosis. [Perform a test infusion by slowly infusing 10 ml of normal saline to check for signs of soft tissue circumferential swelling or increased firmness, or increased resistance to injection. Verify the site Q 3-5 minutes x 3 then Q 30 minutes.
- Remove IO if signs of infection, infiltrations or complications discuss with MD prior to removal

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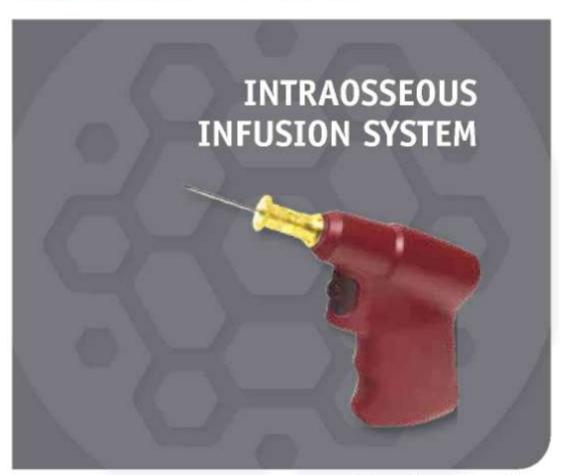
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ANNEX

DIRECTION OF USE





Directions for Use

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

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(Z-IO)

INDICATIONS FOR USE:

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

ADULTS

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

PEDIATRICS

- Proximal tibia.
- Distal tibia.

Proximal humerus should only be used in patients whose 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 48 hours, prosthetic limb or joint).

WARNINGS AND PRECAUTIONS:



CAUTION: Use aseptic technique.

CAUTION: Check skin adipose and muscle thickness before insertion.

CAUTION: Increased dwell time may lead to increased complications.

CAUTION: Use caution with chemotherapeutic agents.

CAUTION: Monitor insertion site frequently for extravasation.

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.

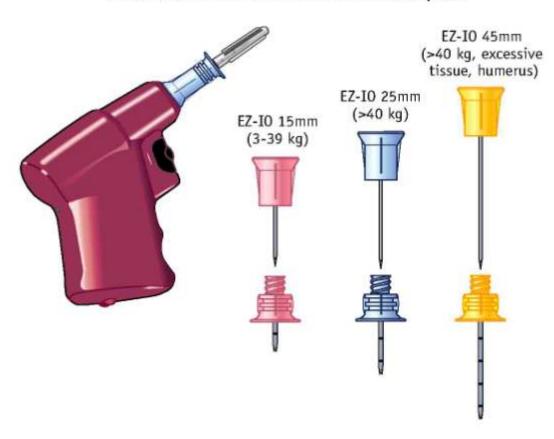


STORAGE: -20°C to 50°C (-4°F to 122°F).

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.
- · Sterile, non-pyrogenic, in protective packaging.
- · Intended for use with EZ-IO Power Driver.

EZ-IO Power Driver and Needle Sets: Description



FZ-I®

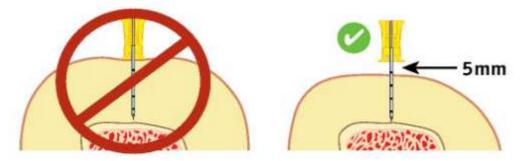


- 1. Clean insertion site per hospital protocol.
- 2. Remove needle safety cap.

IMPORTANT: Only handle Needle Set by the plastic hub.

IMPORTANT: Control patient movement prior to and during procedure.

- 3. Gently press Needle Set through skin until tip touches bone.
- 4. At least 5mm of the catheter must be visible.



5. Squeeze Driver trigger and apply gentle, steady pressure. Release trigger when sudden "give" or "pop" is felt, indicating entry into medullary space. Humerus site: To improve stability, needle should be advanced 2 cm after contact with bone. In adults, advance needle until catheter hub is against the skin.



IMPORTANT:

Use gentle-steady pressure. DO NOT USE EXCESSIVE FORCE. Allow Needle Set rotation and gentle downward pressure to penetrate bone.

Note: If 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.

Remove Power Driver and stylet; confirm catheter stability.

IMPORTANT:

Confirm placement with at least three of the following four methods:

- Stability of catheter
- · Ability to aspirate
- Physiologic or pharmacologic changes
- Adequate flow rate
- Use of the EZ-Stabilizer is strongly recommended for the humerus site and for pediatrics.
- 8. Attach EZ-Connect® extension set.

Prior to attaching the EZ-Connect®:

- a. Ensure clamp is open.
- b. Prime set and purge air.
- c. Attach set firmly to catheter hub.

DO NOT ATTACH A SYRINGE DIRECTLY TO THE EZ-IO CATHETER HUB EXCEPT WHEN DRAWING BLOOD FOR LABORATORY ANALYSIS (STABILIZE NEEDLE SET).

Flush the EZ-IO catheter with normal saline (10ml for adults; use appropriate weight-based dose for smaller patients).

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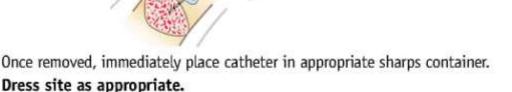
IMPORTANT:

- · Prior to flush, confirm placement as noted in Step 6.
- For patients responsive to pain, consider 2% lidocaine IO without preservatives or epinephrine (cardiac lidocaine) prior to flush.
 Follow institutional protocols/policy.
- Local anesthetics intended for the medullary space must be administered very slowly until 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.

CAUTION: Frequently monitor the insertion site for extravasation.

- Apply EZ-IO wristband; apply dressing if needed.
- 11. To remove catheter from patient:

Attach Luer-lock syringe. Rotate syringe and catheter clockwise while using traction to withdraw catheter – DO NOT ROCK OR BEND THE CATHETER DURING REMOVAL.



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

Education and training materials available at Vidacare.com



Vidacare.com

EMERGENCY NUMBER:

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For further assistance, contact your local Vidacare distributor: Vidacare.com



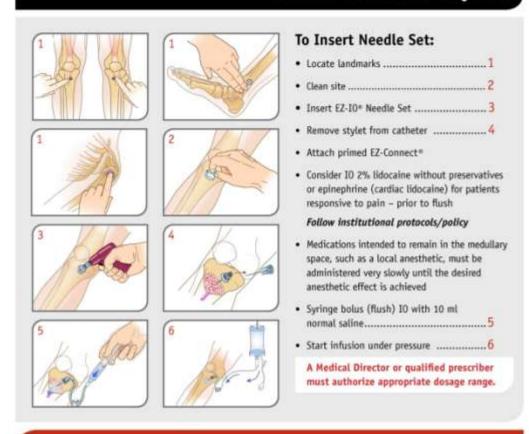
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Infusion System are trademarks of the Vidacare Corporation.





Intraosseous Infusion System



Do Not Leave the EZ-IO catheter in for more than 24 hours.



To Remove Catheter:

- · Stabilize patient's extremity
- · Connect sterile Luer lock syringe to hub of catheter
- · Rotate catheter clockwise while pulling straight back
- When catheter has been removed, immediately place in appropriate biohazard container.

DO NOT ROCK the catheter while removing. Rocking or bending the catheter may cause the catheter to separate from the hub.

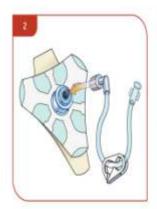
Emergency contact in US or Canada call: 1-800-680-4911

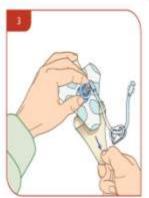
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