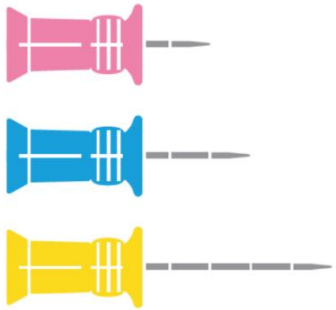
ARROW® EZ-IO®
INTRAOSSEOUS VASCULAR ACCESS

EZ-IO® INTRAOSSEOUS VASCULAR ACCESS NEEDLES

Instructions for Use



English

Teleflex®

INDICATIONS FOR USE:

For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent or medically necessary cases for up to 24 hours.

INSERTION SITES:

ADULTS (≥22 years old): proximal humerus, proximal tibia, distal tibia
PEDIATRICS (≤21 years old): proximal humerus, proximal tibia, distal tibia, distal femur

For patients ≥ 22 years old, the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

CONTRAINDICATIONS FOR USE:

- Fracture in target bone.
- Previous, significant orthopedic procedure at the site, prosthetic limb or joint.
- IO access (or attempted IO access) in targeted bone within past 48 hours.
- Infection at the area of insertion.
- Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks.

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

CAUTIONS:

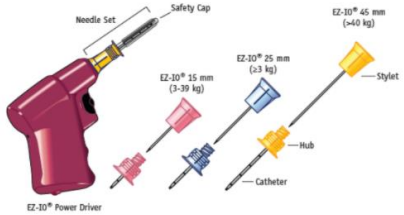
- Use aseptic technique.
- Check skin, adipose and muscle thickness before insertion.
- Extra care should be taken during insertion and site monitoring when used in patients with bone diseases that increase the likelihood of fracture, extravasation and dislodgement.
- Do not recap Needle Sets or reconnect separated components. Use biohazard and sharps disposal precautions. Re-use of contents may cause cross-contamination, leading to patient risk and complication(s).
- Before administering vesicant, toxic, or highly-concentrated drugs, check the IO Catheter again for placement and patency.
- Use caution with chemotherapeutic agents.
- Monitor IO site/limb/infusion frequently for any signs of extravasation/infiltration, localized inflammation, changes in infusion rates or dislodgement, particularly in the first half hour after insertion, anytime the IO catheter is manipulated or after patient transport, and during infusion of vasopressors, vesicants, and bolus or with high infusion rates and high pressure, but at least hourly during all infusions. This is especially important for all high-risk patients (elderly, pediatric, patients in shock, coagulopathies, decreased immunity, obese, etc).
- Post-IO catheter removal, a delayed complication can occur. Instruct patients and caregivers to return patient to the hospital for any problems in the limb to include a change in the limb appearance (discoloration, swelling), pain, warmth, paresthesias, fever, and prolonged discomfort.

- Complications for individuals with comorbidities that increase risk of infection or other IO access related complications may be at a higher rate than in patients lacking co-morbidities. This risk may increase with a longer dwell/ time the device is in place.
- Stylet and Catheter are **NOT** MRI compatible.
- Do not leave the Catheter inserted for longer than indicated.
- Needle Sets are single use only; serious medical consequences (e.g. life-threatening infection) and reduced performance (e.g. blunted needles) may occur if compliance to this warning is not followed.
- Failure to follow these instructions and associated clinical educational materials may lead to patient or provider injury.
- IO infusion pain varies from mild to severe. Pain may be mitigated with a slow infusion of preservative-free and epinephrine-free lidocaine, before initial flush; and other analgesics appropriate to each patient's clinical situation.
- Potential side effects include pain, inflammation, bleeding at the insertion site, extravasation, infiltration, infection, osteomyelitis, compartment syndrome.

EZ-IO® NEEDLE SETS: DESCRIPTION

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

EZ-IO® Power Driver and EZ-IO® Needle Sets: Description



Insertion Site Instructions

Adult/Pediatric Proximal Humerus

Internally rotate and adduct the arm using one of the following methods: 1) Place the hand over the abdomen with the arm tight to the body, or 2) place the arm tight against the body and rotate the hand so the palm is facing outward, thumb pointing down. Palpate the surgical neck of the proximal humerus. The insertion site is on the anterolateral part of the arm, 1-2 cm above the surgical neck, in the most prominent aspect of the greater tubercle. Insert needle set into the greater tubercle at an approximately 45-degree angle, as if aiming toward the opposite hip.

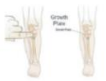
Neonate/Infant/Child Distal Femur

Secure site with leg outstretched to ensure knee does not bend. The insertion site is approximately 1-2 cm proximal to the superior border of the patella and approximately 1 cm medial to the mid-line (depending on patient anatomy). Aim the needle set tip at a 90-degree angle to the bone for insertion.

Adult/Older Child Proximal Tibia

Insertion site is approximately 3 cm below the patella and approximately 2 cm medial to the tibial tuberosity along the flat aspect of the tibia (depending on patient anatomy). Aim the needle set tip at a 90-degree angle to the bone for insertion.

Neonate-Young Child Proximal Tibia



If the tibial tuberosity can be palpated the insertion site is approximately 1 cm medial to the tibial tuberosity. If the tibial tuberosity cannot be palpated, the insertion site is approximately 1-2 cm below the patella and approximately 1 cm medial, along the flat aspect of the tibia (depending on patient anatomy). Aim the needle set tip at a 90-degree angle to the bone for insertion.

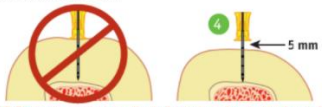
Adult/Older Child Distal Tibia

Insertion site is approximately 3 cm proximal to the most prominent aspect of the medial malleolus (depending on patient anatomy). Palpate the anterior and posterior borders of the tibia to ensure that your insertion site is on the flat center aspect of the bone. Aim the needle set tip at a 90-degree angle to the bone for insertion.

Neonate-Young Child Distal Tibia

Insertion site is approximately 1-2 cm proximal to the most prominent aspect of the medial malleolus (depending on patient anatomy). Palpate the anterior and posterior borders of the tibia to ensure that your insertion site is on the flat center aspect of the bone. Aim the needle set tip at a 90-degree angle to the bone for insertion.

1. Clean insertion site per institutional protocol/policy.
2. Prepare supplies.
   a. Prime EZ-Connect® Extension Set.
      - Unlock clamp.
      - Prime set and purge air.
   b. Open EZ-Stabilizer™ Dressing package.
3. Attach EZ-IO® Needle Set to EZ-IO® Power Driver and remove Safety Cap from Catheter.
   IMPORTANT: Only handle EZ-IO® Needle Set by the plastic Hub.
   IMPORTANT: Control patient movement prior to and during procedure.
4. Push EZ-IO® Needle Set through skin until tip touches bone. 5 mm of the Catheter (at least one black line) must be visible outside the skin.



IMPORTANT: The most accurate determinant of correct needle selection is use of depth markings. Black depth marks on each catheter function as depth measuring guides to determine soft tissue depth overlying bone (see above).

5. Squeeze trigger and apply gentle, steady pressure.
   IMPORTANT: DO NOT USE EXCESSIVE FORCE.
   Note: *If EZ-IO® Power Driver stalls and EZ-IO® Needle Set will not penetrate the bone, operator may be applying too much downward pressure to penetrate bone.*
   Note: *In the event of an EZ-IO® Power Driver failure, disconnect the EZ-IO® Power Driver, grasp the EZ-IO® Needle Set Hub by hand and advance into the medullary space while twisting back and forth.*
6. Advance EZ-IO® Needle Set and release Trigger.
   Pediatrics: Release Trigger when sudden "give" or "pop" is felt, indicating entry into medullary space.
   Adults: Advance EZ-IO® Needle Set approximately 1 cm after entry into medullary space; in proximal humerus for most adults Catheter should be advanced until Needle Hub is flush or against the skin (this may be more than approximately 1 cm).
7. Stabilize Needle Set Hub, disconnect EZ-IO® Power Driver, and remove Stylet.
8. Place Stylet into NeedleVISE® for sharps containment.

Note: *Place the NeedleVISE® on a flat stable surface. Immediately following use of a needle, use a one-handed technique holding the catheter hub, firmly insert the sharp pointed tip straight down into the opening in the NeedleVISE® until it stops. Do not hold NeedleVISE® with free hand. Dispose of opened sharp into NeedleVISE® whether or not it has been used.*

9. 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.*
10. Place EZ-Stabilizer™ Dressing over Catheter Hub.
    Note: *Use of the EZ-Stabilizer™ Dressing is strongly recommended for all EZ-IO® Needle insertions.*
11. For patients responsive to pain, consider 2% preservative-free 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.
12. Attach a primed EZ-Connect® Extension Set to the Hub, firmly secure to Catheter Hub by twisting clockwise, ensure clamp is open.
    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 EZ-Connect® Extension Set valve and let it air dry.*
13. Attach EZ-Stabilizer™ Dressing by pulling the tabs to expose the adhesive and adhere to skin. Secure the affected limb to minimize movement and risk of dislodgement; ambulation is discouraged. Use caution moving patients.
    a. Proximal humerus: Secure arm in place across the abdomen, or in adducted position (with the patient's arm close to body) using immobilizer or alternate method.
    b. Distal Femur: Stabilize extremity and secure site with leg outstretched to ensure knee does not bend using leg board or alternate method.
    c. Proximal and distal tibia: Minimize potential for catheter movement when necessary with use of leg board or alternate method in pediatric patients.
14. Flush the EZ-IO® Catheter with normal saline (0.9% Sodium Chloride)(5-10 mL for adults; 2-5 mL 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.
15. Confirm Catheter placement with the following recommended methods:
    - Stability of Catheter in the bone.
    - Ability to aspirate from flush.
    - Adequate flow rate.
16. Document date/time of insertion and apply wristband.

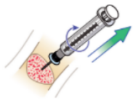
CAUTION: Monitor insertion site frequently for extravasation.

To remove EZ-IO® from patient:

a. Remove EZ-Connect® Extension Set.
b. Lift & remove EZ-Stabilizer™ Dressing.
c. Attach Luer-lock Syringe to Hub of Catheter. Maintain axial alignment and rotate clockwise while pulling straight out. Do NOT rock or bend the Catheter. Improper technique may cause catheter to break.

d. Once removed, immediately place Syringe/Catheter in appropriate sharps container.
e. Dress site per institutional protocol/policy.

Note: *If the Catheter or Needle set breaks during or after placement in the patient, attempt to grasp the catheter that remains in the patient with a hemostat and remove by gently pulling while simultaneously rotating. If broken catheter is not accessible, obtain X-Ray and have physician determine if and how it should be removed as a foreign body.*



For additional clinical educational resources please visit **Teleflex.com/EZIOeducation**

CLINICAL STUDY SUMMARY

A US single-site, prospective clinical IDE trial was performed to study use of the EZ-IO Intraosseous Vascular Access System for up to 48 hours indwelling time; the primary study endpoint was the absence of serious complications resulting from intraosseous (IO) catheter retention over a 48 hour period.

The study participants were either healthy or health-compromised adult volunteers with mild to moderate renal disease (NHANES Stage 1 to 3) and/or controlled diabetes (HbA1C ≤8). There were 121 evaluable subjects enrolled in the study; 79 were in the healthy subset, 39 were in the diabetes only subset, and 3 in the diabetes with renal insufficiency subset. Placement site was randomized with 61 proximal tibia and 60 proximal humerus insertions. Subjects were infused with 0.9% sodium chloride at a rate of 100 mL/hr for the initial eight hours then a rate of 30 mL/hr. Pain control during the study was managed with a slow infusion of preservative-free and epinephrine-free lidocaine before initial flush; and analgesics. An IO aspirate culture was obtained before catheter removal, followed by an x-ray of the site. After 30 days, subjects returned for examination and repeat x-ray.

Three subjects were discontinued from the 48 hour procedural portion of the study: one with pain and left arm swelling after 10 hours; and two adverse events (AE) between 30-32 hours, swelling secondary to extravasation; and leaking at the hub of the device and accidental dislodgement. Four subjects withdrew following IO needle insertion before 48 hours due to inability to control pain or pain and fever.

Study follow-up was performed at 30 days. There were no serious AEs or complications, or unexpected AEs reported for any of the subjects randomized into the study. AEs determined to be related/and or possibly related to the device included: pain, swelling; elevated white blood cell counts and neutrophils; skin demarcation/ scar; fever; local skin allergy; and vasovagal response during initial insertion.

Under the conditions of the study, IO access can be maintained for 48 hours without significant risk of serious adverse events. Pain associated with catheter dwell and infusion can be well-managed, and a slow infusion of 30 mL/hour maintains patency for 48 hours.

Education and training materials available at **ArrowEZIO.com**

ArrowEZIO.com

EMERGENCY NUMBER:

1.800.680.4911

Teleflex®

Customer Service: 1.866.479.8500

Manufactured for:
Teleflex Medical
IDA Business & Technology Park,
Dublin Rd, Athlone,
Co. Westmeath, Ireland

MD Medical Device | No Sterile Use | MR * MRI Unsafe | Latex Not made with natural rubber latex | Sterile EO Sterilized using ethylene oxide | Do Not Use if Package is Damaged | Do not reuse | Do not resterilize | Keep Away From Sunlight | Keep Dry | Caution

Rx only.

CE 2797 The System Conforms to the Medical Device Directive (93/42/EEC)

Consult Instructions for use

IAR001SG-R00