

Arrow[™] EZ-IO[™]

Intraosseous Vascular Access System Procedure and Competency Validation Template

Please refer to Instructions for Use (IFU) on all products prior to use.

I. PURPOSE:

To provide procedural guidance and skills validation for establishment of intraosseous vascular access using the Arrow[™] EZ-IO[™] Intraosseous Vascular Access System.

□ Indications for Use:

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

Adults	Paediatrics
Proximal humerus	Distal Femur
Proximal tibia	Proximal humerus
Distal tibia	Proximal tibia
	Distal tibia

□ Contraindications:

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

□ EZ-IO[™] System equipment/supplies:

- EZ-IO[™] Power Driver
- EZ-IO[™] Needle Set
- EZ-Connect[™] Extension Set
- EZ-Stabilizer[™] Dressing (plus pack inclusion)
- NeedleVISE[™] Sharps Block for sharps containment

□ Additional equipment/supplies needed:

- Non-sterile gloves
- Insertion site cleanser (per institutional protocol/policy)
- Luer lock syringe with sterile normal saline flush (5-10 mL for adults, 2-5 mL for infant/child)

□ Additional equipment/supplies if indicated/ordered:

- 2% preservative-free and epinephrine-free lidocaine (intravenous lidocaine), following physician order, institutional protocols and policy
- Intravenous fluid
- Infusion pressure pump or pressure bag, tubing
- Supplies for lab samples

Preparation:

- Explain procedure to patient/family when possible
- Obtain assistance as needed
- Wash hands in preparation for aseptic technique

□ Insertion site identification:

Palpate site to locate appropriate anatomical landmarks for needle set placement and to estimate soft tissue depth overlying the insertion site. Utilise the correct technique below based on patient and site selected:

□ Proximal Humerus (Adult/Paediatric)

Adduct and internally rotate the arm. To landmark on the anterior shoulder, palpate the greater tubercle by letting it sink into the palm of your hand. Insert needle at this landmark at an approximate 45-degree angle as if aiming toward the opposite hip.

Distal Femur (Neonate/Young Child)

With the leg midline, secure site with leg outstretched to ensure knee does not bend The insertion site is midline, approximately 1-2 cm proximal to the superior border of the patella. Aim the needle set tip at a 90-degree angle to the bone for insertion. Ensure you check for the presence of at least one black line prior to engaging the driver.

Distal Femur (Older Child)

With the leg mid-line, secure site with leg outstretched to ensure knee does not bend. The insertion site is mid-line, approximately 5 cm proximal to the superior border of the patella. Aim the needle set tip at a 90-degree angle to the bone for insertion. Ensure you check for the presence of at least one black line prior to engaging the driver.

Proximal Tibia (Adult/Older Child)

Extend the leg. Insertion site is approximately 2 cm medial to the tibial tuberosity along the flat aspect of the tibia (depending on patient anatomy). If the tibial tuberosity is not present; with the leg extended, the insertion site is approximately 3 cm below the inferior border of the patella and approximately 2 cm medial, along the flat aspect of the tibia (depending on patient anatomy). Aim the needle at a 90-degree angle to the bone for insertion.

Proximal Tibia (Neonate/Young Child)

Extend the leg. 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.

Distal Tibia (Adult/Older Child)

Insertion site is approximately 3 cm proximal to the most prominent aspect of the medial malleolus. 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.

Distal Tibia (Neonate/Young Child)

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



□ EZ-IO[™] Needle Set selection:

ADULTS: As a general guide, for most patients the 25 mm needle set is the correct length for tibial access. The 45 mm needle set should be considered for the proximal humerus site in most adults and for any site when excessive tissue overlies the insertion site.

PAEDIATRICS: The following is a general guide for needle set selection in paediatric patients

- 15 mm: Proximal and distal tibia insertion in neonates and small infants
- 25 mm: Distal femur insertion in neonates and small infants or all approved sites in children with average tissue
- 45 mm: Proximal humerus in patients weighing greater than 40kg, and other approved sites with excess tissue that exceeds the use of the 25 mm needle set
- *For example, a paediatric patient weighing less than 40 kg, may require the use of the 45 mm needle set when the 25 mm needle set is too short due to excess tissue

Select EZ-IO[®] Needle Set based on patient weight (kg), anatomy, and clinical judgment. The EZ-IO[®] Needle Set is marked with black lines. Prior to drilling, with the EZ-IO[®] Needle Set inserted through the soft tissue and the needle tip touching bone, adequate needle length is determined by the ability to see at least one black line outside the skin.

- EZ-IO[™] 45 mm Needle Set (yellow hub) is indicated for patients ≥40 kg. This needle length should be considered for proximal humerus site in most patients weighing ≥40 kg. To ensure adequate needle length and reduce the occurrence of dislodgement due to inadvertent movement. This needle length should also be considered for patients with excessive tissue over any insertion site.
- EZ-IO[™] 25 mm Needle Set (blue hub) is indicated for patients ≥3 kg
- EZ-IO[™] 15 mm Needle Set (pink hub) is indicated for patients 3-39 kg

□ Insertion:

- Use aseptic technique
- Clean insertion site per institutional protocol/policy
- Prepare supplies
 - Unlock clamp on EZ-Connect[™] Extension Set
 - Prime EZ-Connect[™] Extension Set, purge air
 - Attach EZ-IO[™] Needle Set to EZ-IO[™] Power Driver and remove safety cap



II. ADULT INSERTION TECHNIQUE

Proximal Humerus - Adult:

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

- 1. Push the needle set tip through the skin until the tip rests against the greater tubercle, aim needle at an approximate 45-degree angle as if aiming toward the opposite hip.
 - a. The 5 mm mark, which is the black line closest to the hub, must be visible above skin for needle set length confirmation.
- 2. Squeeze trigger and apply gentle, steady pressure, immediately release the trigger when you feel a sudden "give" or loss of resistance as the needle set enters the medullary space. For most adults, needle set should be advanced until hub is flush or against skin.
- a. Use caution, and do not apply excessive pressure, as this may cause the driver to slow and/or stop

□ Tibia – Adult/Older Child:

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

- 1. Push the needle set tip through the skin until the tip rests against the tibia. Aim the needle set at a 90-degree angle to the bone.
 - a. The 5 mm mark, which is the black line closest to the hub, must be visible above skin for needle set length confirmation.
- 2. Squeeze trigger and apply gentle, steady pressure, immediately release the trigger when you feel a sudden "give" or loss of resistance, as the needle set enters the medullary space.
- a. Use caution, and do not apply excessive pressure, as this may cause the driver to slow and/or stop

III. INFANT/CHILD INSERTION TECHNIQUE

□ Proximal Humerus – Infant/Child:

- 1. Push the needle set tip through the skin until the tip rests against the greater tubercle, aim needle at an approximate 45-degree angle as if aiming toward the opposite hip.
 - a. The 5 mm mark, which is the black line closest to the hub, must be visible above skin for needle set length confirmation.
- 2. Squeeze trigger and apply gentle, steady pressure, immediately release the trigger when you feel a sudden "give" or loss of resistance as the needle set enters the medullary space.

a. Use caution, and do not apply excessive pressure, as this may cause the driver to slow and/or stop b. Avoid recoil – do NOT pull back on the driver when releasing the trigger.

□ Femur and Tibia – Infant/Child:

- 1. Push the needle set tip through the skin until the tip rests against the tibia or femur. Aim the needle set at a 90-degree angle to the bone.
 - a. The 5 mm mark, which is the black line closest to the hub, must be visible above skin for needle set length confirmation.
- 2. Squeeze trigger and apply gentle, steady pressure, immediately release the trigger when you feel a sudden "give" or loss of resistance, as the needle set enters the medullary space.

a. Use caution, and do not apply excessive pressure, as this may cause the driver to slow and/or stop b. Avoid recoil – do NOT pull back on the driver when releasing the trigger



IV. MANUAL INSERTION

- If the EZ-IO[™] Power Driver LED is solid green when trigger is activated, the driver has sufficient power. If EZ-IO[™] Power Driver is stalling and the EZ-IO[™] Needle Set will not penetrate the bone, operator may be applying too much downward pressure to penetrate bone.
- If the EZ-IO[®] Power Driver LED is blinking red when the trigger is activated, the driver has less than 10% of battery life remaining. Purchase and replace the EZ-IO[®] Power Driver. Proceed to Manual Insertion below.
- If the EZ-IO[™] Power Driver LED will not light, or will briefly light, when the battery has expired. Use a backup driver or proceed to manual insertion below.
- 1. Disconnect the EZ-IO[™] Power Driver.
- 2. Grasp the EZ-IO[®] Needle Set Hub by hand and advance into the medullary space while twisting back and forth.

V. INSERTION COMPLETION

- 1. Stabilise Needle Set Hub, disconnect EZ-IO[™] Power Driver, and remove stylet
- 2. Place stylet into NeedleVISE[™] Sharps Block for sharps containment
 - a. Place the NeedleVISE[®] Block on a flat stable surface. Immediately following use of a needle, use a one-handed technique holding the stylet hub, firmly insert the sharp pointed tip straight down into the opening in the NeedleVISE[®] Block until it stops. Do not hold NeedleVISE[®] Block with free hand Dispose of opened sharp into NeedleVISE[®] Block whether or not it has been used.
- 3. Obtain samples for lab analysis, if needed (stabilise cannula)
 - a. Only attach a syringe directly to the EZ-IO[™] Cannula Hub when drawing blood for laboratory analysis, administering anesthetic or remova
- 4. Place EZ-Stabilizer[™] Dressing over cannula hub
- 5. For patients responsive to pain, consider 2% preservative-free and epinephrine-free lidocaine (intravenous lidocaine), follow institutional protocols/policy*
- 6. Attach a primed EZ-Connect[®] Extension Set to the hub, firmly secure to cannula hub by twisting clockwise, ensure clamp is open
- 7. Pull the tabs off the dressing to expose the adhesive and adhere to the skin
 - Flush the EZ-IO" Cannula with normal saline (0.9% Sodium Chloride: 5-10 mL for adults, 2-5 mL infant/child) a. Prior to flush, consider slight aspirate for visual confirmation of bone marrow.
 - b. Inability to withdraw/aspirate blood from the cannula hub does not mean the insertion was unsuccessful
- 9. Administer medications and fluids as ordered and pressurise fluids to 300 mmHg for maximum flow
- 10. Verify placement/patency prior to all infusions. Use caution when infusing hypertonic solutions, chemotherapeutic agents, or vesicant drugs
- 11. Stabilise the affected limb and monitor site for extravasation or other complications.

a. For proximal humerus insertions: Secure arm in place across the abdomen, or in adducted position (with the patient's arm close to body) using immobiliser or alternate method. Do not raise arm above 45 degrees to prevent inadvertent needle dislodgement

b. For distal femur insertions: Stabilise extremity and secure site with leg outstretched to ensure knee does not bend using leg board or alternate method to prevent inadvertent needle dislodgement.

- c. For proximal and distal tibia insertions: Minimise potential for cannula movement when necessary with use of leg board or alternate method in paediatric patients.
- 12. Document date and time on pink wristband and place on patient



8.

VI. IO INFUSION PAIN MANAGEMENT USING 2% LIDOCAINE (preservative-free and epinephrine-free)*

Review lidocaine manufacturer's IFU prior to administration and observe recommended cautions/contraindications. With the stabilizer in place, carefully attach syringe directly to IO cannula luer-lock hub, without extension set in place.

- 1. Slowly infuse initial dose of lidocaine over 120 seconds and allow to dwell for 60 seconds
 - Adult: initial dose 40 mg
 - Infant/Child: initial dose 0.5mg/kg (NOT to exceed 40 mg)
 - Flush IO cannula with normal saline
 - Adult: Adult flush: 5-10 mL
 - Infant/Child flush: 2-5 mL
- 2. Slowly infuse lidocaine (half of initial dose) over 60 seconds
- 3. Attach extension set primed with normal saline and flush

For continued analgesia related to intraosseous pain, follow institutional protocol/policy.

VII. REMOVAL TECHNIQUE

- 1. Remove EZ-Connect[™] Extension Set
- 2. Lift and remove EZ-Stabilizer[™] Dressing
- 3. Stabilise cannula hub and attach a Luer lock syringe to the hub
- 4. Holding the syringe and hub together as one unit, and maintaining axial alignment, twist clockwise and pull straight out. Do not rock or bend the cannula.
- 5. Dispose of cannula with syringe attached into sharps container
- 6. Dress site per institutional protocol/policy

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*DISCLAIMER: Observe cautions/contraindications for lidocaine, confirm dose per institution. Selection and use of any medication, including lidocaine, given IV or IO is the responsibility of the treating physician, medical director, or qualified prescriber and is not an official recommendation of Teleflex Incorporated. The information provided is a summary of information found in the cited reference materials. This information is not intended to be a substitute for sound clinical judgment or your institution's treatment protocols. Teleflex Incorporated is not the manufacturer of lidocaine. Users should review the manufacturer's instructions or directions for use and be familiar with all indications, side effects, contraindications, precautions and warnings prior to administration of lidocaine or any other medication. Teleflex Incorporated disclaims all liability for the application or interpretation of this information in the medical treatment of any patient. Any health care provider using this material assumes full responsibility for the medical care and treatment of their patients. For additional information please visit www.eziocomfort.com.

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Arrow[™] EZ-IO[™] Intraosseous Vascular Access System Skills Evaluation

	PERFORMANCE CRITERIA	SUCCESSFUL	ADDITIONAL TRAINING NEEDED
1	Describe indications and contraindications		
2	Demonstrate landmarking with insertion site identification for adult sites		
 3	Demonstrate landmarking with insertion site identification for paediatric sites		
4	Describe needle set selection		
 5	Demonstrate use of the needle set black 5 mm line		
6	Describe needle set pack contents and other required supplies		
7	Describe angle of insertion for proximal humerus		
8	Describe angle of insertion for the tibia and femur (paediatric)		
9	Demonstrate insertion (preparation through clinical use)		
10	Demonstrate lidocaine administration for associated pain		
11	Describe use of fluids, medication, and labs		
12	Describe care and maintenance and potential complications		
13	Demonstrate and describe needle set removal		
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