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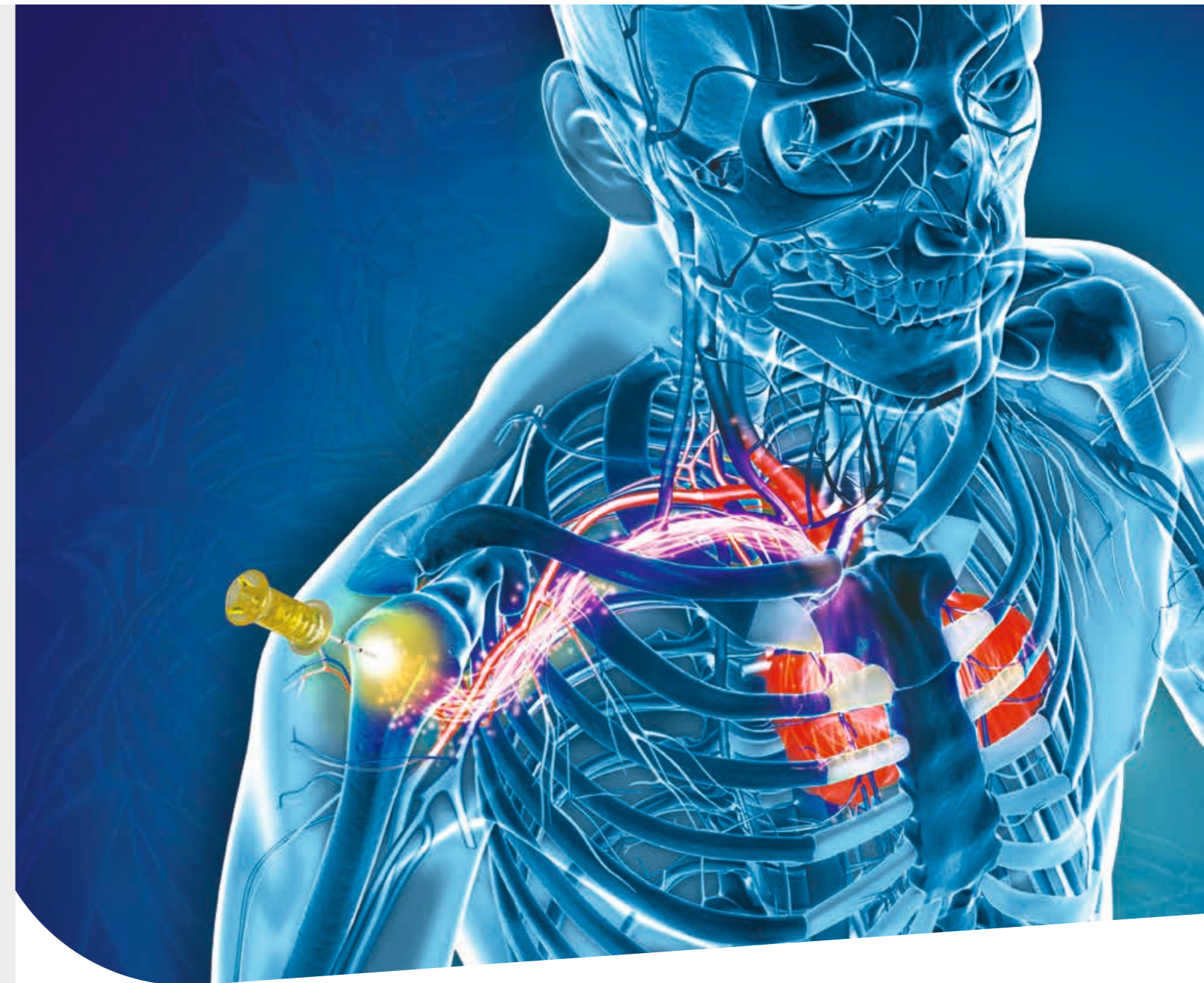
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Arrow EZ-IO Intraosseous Vascular Access System 2020 The Science and Fundamentals of Intraosseous Vascular Access including frequently asked questions

Teleflex Global Research and Scientific Services, a Division of Clinical and Medical Affairs

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For patients > 12 years old use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

Introduction

We are pleased to provide you with the third edition of “The Science and Fundamentals of Intraosseous Vascular Access”. This document represents the body of knowledge garnered from years of research (clinical and preclinical), laboratory experimentation, clinical experience (end-users and researchers), and expert opinion (intraosseous experts and subject matter experts).

The document is divided by topics into several sections. The first part of each section contains a list of short, concise responses to the most commonly asked questions regarding IO vascular access. Where more detailed information and research is available, the reader is directed to the appropriate section. For clarity, most citations and references are confined to the expanded, detailed sections.

Citations which are followed by the superscript¹⁵ indicate studies that have been sponsored in part or conducted by Teleflex Incorporated.

A superscript^{E0} after a statement or title signifies information based on ‘Expert Opinion’ and will occur after relevant statements (in lieu of a cited reference). Unless otherwise noted, expert opinion is provided by Teleflex Clinical and Medical Affairs.

The authors of this document have examined the cited sources and made every effort to assure the information provided is reliable, complete, and in accord with the standards of current practice at the time of publication. Use of IO access devices is the responsibility of the treating clinician, medical director, or qualified prescriber.

We hope these answers will assist Teleflex team members and clinicians in taking full advantage of the benefits – and minimising the risks – of IO vascular access and use of the Arrow EZ-IO Intraosseous Vascular Access System.

This document is disseminated for medical and scientific/educational purposes only, and some cited studies may contain references to indications for IO access or insertion sites that have not been cleared or approved by the U.S. Food and Drug Administration (FDA) or regulatory authorities outside of the U.S. relating to the EZ-IO Device (manufactured/marketed/distributed by Teleflex Incorporated). This information should not be construed to suggest that any Teleflex product may or should be used in any manner that differs from its FDA-cleared or CE mark registered Indications/Directions for Use.

Indications/Contraindications and General IO Use

When Can the Arrow EZ-IO Intraosseous Vascular Access System from Teleflex Be Used?

Indications for the Arrow EZ-IO Intraosseous Vascular Access System:

- The Arrow EZ-IO Intraosseous Vascular Access System provides intraosseous access in the proximal tibia, distal tibia, and humeral head (proximal humerus) of adult and paediatric patients, and the distal femur in paediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours in non-CE indicated markets and up to 72 hours in CE indicated markets.

Contraindications for the EZ-IO Device:

- Fracture in target bone
- Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks (e.g. may also be due to muscularity or variations in body habitus or an under-developed humerus in an infant/small child)
- Infection at area of insertion site
- Previous, significant orthopedic procedure at the site, prosthetic limb, or joint
- IO access (or attempted IO access) in targeted bone within past 48 hours

In What Type of Clinical Scenarios is IO Vascular Access Used?

The following is an example of some of the types of emergent/urgent situations or patient conditions where intravenous access is difficult or impossible to obtain in which IO vascular access may be beneficial:

- Anaphylaxis
- Altered level of consciousness
- Bridge to central venous catheter placement
- Burns
- Cardiac arrest
- Cardiac arrhythmias
- Cardiac compromise
- Dehydration
- Diabetic ketoacidosis
- Drug overdose
- End stage renal disease
- Haemodynamic instability
- Hypovolemia
- Major trauma
- Rapid sequence intubation necessity
- Respiratory compromise/arrest
- Seizures/status epilepticus
- Sepsis
- Shock
- Sickle cell crisis
- Stroke
- Therapeutic hypothermia indication

Non-urgent but medically necessary situations or patient conditions where intravenous access is difficult or impossible to obtain in which IO vascular access may be beneficial:

- Antibiotic therapy needed
- Chest pain
- Dehydration
- Metabolic disorders
- Need for general anaesthesia
- Patients in pain
- Patients requiring access for induction
- Sedation for procedures needed
- Surgical procedures

Can the EZ-IO Device Be Used in the Sternum?

The Arrow EZ-IO T.A.L.O.N. (Tactically Advanced Lifesaving Intraosseous Needle) Needle Set was originally designed for use by the military and tactical medical teams. For EZ-IO Products, only the EZ-IO T.A.L.O.N. Needle Set, as directed in the Instructions for Use specific to the sternum, may be used safely in the sternum. Neither the EZ-IO Needle Sets nor the EZ-IO Driver should ever be used for sternal insertion. Refer to the indication for use in the Instructions for Use for the EZ-IO T.A.L.O.N. Needle Set.

What is Off-Label Use of the EZ-IO Device?

Off-label use is defined as use of a medical device for an indication not specifically approved or cleared by the U.S. Food and Drug Administration (FDA) or governing regulatory body specific to countries outside of the United States. Physicians (or qualified prescribers) may prescribe, order, or use drugs and devices for indications not approved or cleared by the FDA according to their best medical judgment; however, the manufacturing company is prohibited from any promotion of the off-label use. Teleflex does not recommend, promote, or endorse off-label use of the EZ-IO Intraosseous Vascular Access System or any other product manufactured or distributed by Teleflex.

Can Nurses and Medics Perform IO Insertions?

Every state in the U.S. and most other countries have laws and regulations that govern the medical procedures licensed personnel may perform within their respective scope of licensure. These laws, regulations and directives are occasionally modified as new medical technology becomes standard and accepted within the healthcare industry.

RN: A licensed, qualified and trained registered nurse is permitted to place and manage IO devices, if it is determined by regulation, position statement or decision-making model to be within that professional's scope of practice. The appropriate organisational officials, chief nursing officer/nurse supervisor, hospital, or state regulatory official should be consulted to determine whether placement and use of IO devices is currently within an individual's scope of practice.

Pre-hospital Providers: Each state permits a licensed, trained, and qualified EMS professional to place and use IO devices upon the order of a medical director. The appropriate regulatory agency, medical director, and system protocols should be consulted to determine if placement and management of IO devices is currently within an individual's scope of practice.

Do Professional Organisations Support IO Vascular Access for Clinical Applications?

A variety of professional organisations have developed position statements and guidelines supporting IO vascular access for their respective specialties.²⁻⁹

Is Special Training or Certification Required Prior to Using the EZ-IO Device?

There is no official "certification" process unless mandated by an agency/organisation, medical director, or hospital. The EZ-IO Needle Set is similar to a peripheral intravenous (IV) catheter in that specific training must occur in order to use the device safely and correctly. Teleflex offers a comprehensive training programme for the EZ-IO Device and recommends completion prior to using the device. Online training information is available at www.teleflex.com/ezioeducation. Additionally onsite training can be requested through your local Teleflex representative or by email: CMARrequest@teleflex.com.

References:

- 1 Food and Drug Administration. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices Information Sheet. Internet: Accessed: 05/30/2017. Available at: <https://www.fda.gov/regulatoryinformation/guidances/ucm126486>
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Anatomy and Physiology of the IO Space

How Does the IO Vascular Access Route Work?

IO vascular access catheters are usually placed in the proximal and distal ends (epiphyses) of long bones due to the thinner compact bone and abundance of cancellous (spongy) bone at these sites. Within the epiphysis of the medullary space lies a vast system of blood vessels. When accessed with an IO catheter, infusions pass from the medullary space through the vascular system into the central circulation.

Which Insertion Site Works Best?

IO site selection depends on clinical needs, patient age, size, anatomy, presenting condition, ability to locate anatomical landmarks, environment, clinical judgment, and experience. [See "Selection of Appropriate Insertion Site and Needle Set", page 21.]

Anatomy

Within the epiphysis (proximal and distal end) of the medullary space of the bone lies a vast system of blood vessels and sinusoids, the Haversian canals and Volkmann canals, which function as rigid non-collapsible canals. During IO infusion to this large network, blood and fluid travel quickly through this component of the vascular system out nutrient and emissary vessels to reach the central circulation.²³

See Figure 1 below and Figure 2 on following page.

IO vascular access catheters are placed in the epiphyses of long bones such as the humerus and tibia where compact bone is relatively thin and there is an abundance of cancellous (spongy) bone. This area of the bone allows for easier entry through the cortex of the bone, with rapid access into the IO vasculature.

Figure 1

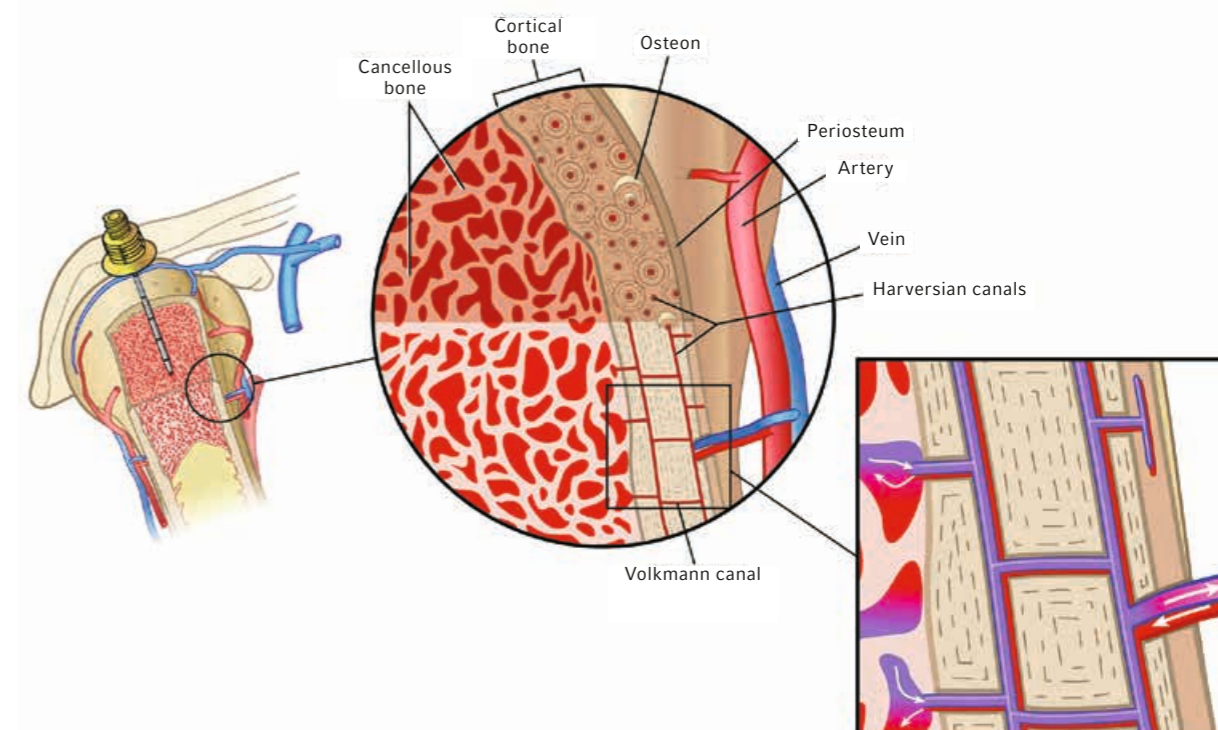
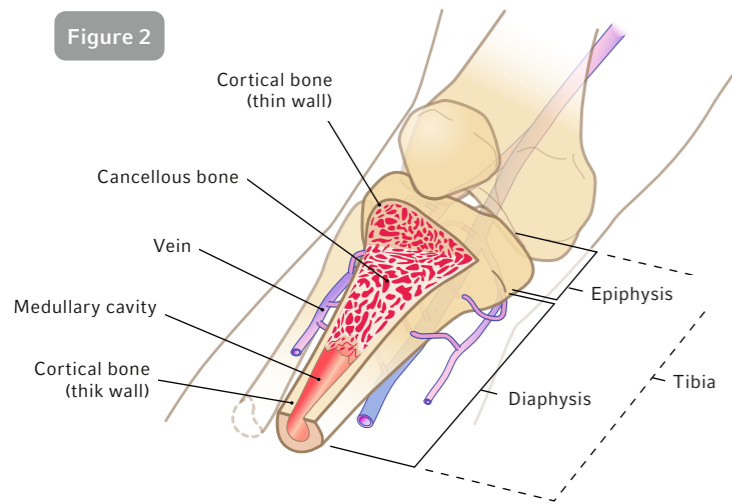


Figure 2



Physiology

A 25-patient clinical study published in 2008 compared the pharmacokinetics of IO access using an implantable IO device to IV administration of morphine sulfate in adults. The investigators reported no differences between IO and IV administration of morphine for several pharmacokinetic parameters, including maximum plasma concentration, time to maximum plasma concentration, and area under plasma concentration-time curve.³

In a healthy adult volunteer study, contrast media was injected through the proximal humerus site and captured under fluoroscopy as it entered the heart. The mean time it took from injection at the insertion site to visualise contrast entry from the superior vena cava into the right atrium was 2.42 seconds.⁴

Many preclinical and clinical studies support the safety, efficacy and ease of use of the IO vascular access route for administration of a variety of fluids and medications in multiple applications.⁵⁻¹⁷

For additional resources, a comprehensive bibliography listing intraosseous vascular access publications is available at:
http://www.teleflex.com/en/usa/ezioeducation/documents/General_IO_Bibliography.pdf

Intramedullary Pressure

Two preclinical studies demonstrated pressure in the IO medullary cavity measures approximately 22% to 25% of arterial pressure without significant difference between IO sites tested.^{18,19} A clinical pilot study by the same researchers was conducted with intensive care unit patients to measure IO pressures and determine their relationship to blood pressure obtained using an external blood pressure cuff. Investigators concluded that in severely ill and injured patients, IO pressure can be reliably obtained and appears to be 35% to 40% of blood pressure readings obtained via an external blood pressure cuff.²⁰

During Cardiopulmonary Resuscitation (CPR)

Guidelines. As early as 1992, a statement for the Advanced Life Support Working Party of the European Resuscitation Council (ERC) describes the IO route as a rapid route to central circulation and a viable route for drug administration during CPR.²¹ In a 1996 article, physicians from Japan described successful experiences using the IO route for resuscitation medications during CPR.²² Since 2005, the American Heart Association acknowledges the intraosseous route to enable delivery similar to peripheral access and advocates use of the intraosseous route for medication administration as a priority after CPR and rapid defibrillation. It states IO access is reasonable if IV access is not readily available.²³ Since 1988, Pediatric Advanced Life Support (PALS) guidelines recommend immediate intraosseous access in cardiac arrest if no IV access is in place; limiting number of attempts for venous access; and establishing intraosseous access if IV access cannot be attained quickly. PALS states “IO access can be quickly established with minimal complications by providers with varied levels of training”; and recommends limiting time spent establishing IV access. PALS notes “and it is useful as the initial vascular access in cases of cardiac arrest (Class I, LOE C). Many intravenous medications can be administered intraosseously, including epinephrine, adenosine, fluids, blood products, and catecholamines (as referenced in clinical literature). Onset of action and drug levels for most drugs are comparable to venous administration.”²⁴ The 2015 ERC guidelines reiterate that IO access is a rapid, safe, and effective vascular access route; and note that the onset of action and time to achieve adequate plasma drug concentrations are similar to that achieved via the central venous route and recommends it as a viable route for drug administration during CPR.²⁵

Preclinical Studies

Preclinical studies dating to 1990s have studied the efficacy of IO access during CPR.²⁶ In a series of preclinical swine studies, Hoskins et al. evaluated efficacy of the IO route compared to other IV access routes. In the early studies researchers demonstrated that fluid infused into the IO space gains access to the central circulation ranging from less than one minute for the sternal IO site to less than two minutes from the tibia, yielding physiologically significant levels even during CPR.^{27,28} The authors suggested that results demonstrated IO access equivalence to IV access during CPR. The same investigators completed a follow up study evaluating the sternal and humeral IO (HIO) routes and concluded the proximal humerus and sternal IO routes were comparable to central venous drug delivery during CPR.^{29,30}

In a 2011 preclinical study by Zuercher et al., 30 swine in ventricular fibrillation with continuous chest compressions received IO epinephrine, IV epinephrine, or placebo. Return of spontaneous circulation (ROSC), 24-hour survival, and 24-hour survival with good neurological outcome were evaluated. Results showed ROSC to be nearly universal for the IV and IO groups with no differences between rates; 24-hour survival was substantially more likely in the IO group than the IV group; survival with good neurological outcome was more likely in the IO group than the IV group.³¹

Another swine study, by Burgert et al., compared epinephrine concentrations administered via the tibial IO (TIO), sternal IO, and IV routes during CPR. The IV route of administration of 1 mg of epinephrine resulted in a serum concentration greater than the tibial route and sternal route, respectively. The times to peak concentration was similar for IV and sternal IO groups but delayed for the tibial route. Authors concluded that due to limitations of their study the guidelines of administering 1 mg of epinephrine via the IO route should not be changed; further studies using larger sample size, larger volume flush, arterial blood samples, and the use of a more precise method of measuring serum epinephrine should be done.³²

A 2015 follow-up prospective preclinical study by some of the same investigators was done to determine the effects of HIO and IV epinephrine administration during cardiac arrest on pharmacokinetics, ROSC, and odds of survival. There were no significant differences in ROSC, maximum concentration, except at 30 seconds, and time-to-concentration-maximum between the HIO and IV groups. Significant differences existed between the experimental groups and the control. The HIO delivered a higher concentration of epinephrine

than the IV route at 30 seconds, which they noted may be a survival advantage. Authors suggested clinicians consider using the IO route to administer epinephrine when IV access is unobtainable.³³

A 2015 preclinical randomized controlled trial (RCT) by Burgert et al. evaluated the relationships between the anatomical distance of IO epinephrine and measures of resuscitative outcome in an adult swine model of ventricular fibrillation (VF). There were no significant differences between the HIO, TIO, and IV groups relative to the occurrence of ROSC, 30-minute post-ROSC survival, and time to ROSC. The anatomical distance of IO epinephrine injection from the heart did not affect short-term measures of resuscitative outcome in an adult swine model of VF including the occurrence of ROSC, 30-minute post-ROSC survival, and time to ROSC. Rapidly administered epinephrine, irrespective of route of administration, increased the chance of ROSC and survival to 30 minutes post-ROSC in this study.³⁴

A number of preclinical studies published in 2016 studied IO delivery of medications during CPR on ROSC and their pharmacokinetic qualities in a swine model. Wimmer et al. compared pharmacokinetics of IO humeral vasopressin and ROSC with IV access and a control of defibrillation and CPR only. All IO access animals had ROSC; hemodynamic and pharmacokinetic parameters and survivability were no different for the IO and IV groups. Survivability was 33 times higher for the IO group versus the control group ($p=0.03$).³⁵ Amiodarone given by the IV route was compared to administration by the IO route via the tibial, humeral, and sternal sites in three other studies. In a comparison of the HIO and IV routes, Holloway et al. found no difference in time to ROSC or rate, time to maximum concentration (T_{max}) ($p=0.501$) or in maximum plasma drug concentration (C_{max}) ($p=0.232$).³⁶ In a comparison of IV to TIO administration of amiodarone investigators found no significant differences for the same endpoints between IO and IV.³⁷ The sternal route was compared to IV in a hypovolemic cardiac arrest swine model for C_{max} , T_{max} , and ROSC rates and times. No significant differences were found in this study between IO and IV administration.³⁸

Two recently published preclinical studies addressed IV versus IO delivery of resuscitative medications during CPR. Wong 2016 examined the differences in pharmacokinetics and pharmacodynamics of TIO and IV-delivered epinephrine during cardiac arrest and CPR. There were no significant differences between IV versus TIO epinephrine in achieving ROSC, time to ROSC, and C_{\max} (the maximum concentration). Authors suggest that in the context of ROSC, epinephrine delivered via the TIO route is a clinically relevant alternative to IV administration.³⁹ In another study using a swine model, Fulkerson et al. completed a randomized prospective study to examine the differences in pharmacokinetics and pharmacodynamics of TIO and IV-delivered vasopressin during cardiac arrest and CPR until ROSC was achieved. No difference was noted for ROSC between TIO and IV delivered vasopressin. Authors concluded use of IO access could avoid the time delay associated with IV access, is effective for treatment of hypovolemic cardiac arrest and should be first line for rapid vascular access.⁴⁰

Burgert 2017 reported data from a preclinical study evaluating the pharmacokinetics of HIO and IV vasopressin and the ROSC in a swine model of ventricular fibrillation cardiac arrest. For the parameters of occurrence of ROSC, odds of ROSC, time to ROSC, C_{\max} , T_{\max} , and plasma concentrations over time, the IO and IV routes results were comparable.⁴¹

Clinical Studies

Clinical studies reporting on IO vascular access most often report the ease of access and success rates with few reporting on rates of ROSC.⁴²⁻⁴⁶ Due to the anatomical characteristics of the most commonly accessed IO insertion sites in the extremities, IO access can be obtained without or with minimal interruption of chest compressions.¹⁶

Ross 2016 compared IO versus IV access for the time to epinephrine for out of hospital cardiac arrests (OOHCA). There were 2,601 cases of IO usage and 55 cases of PIV usage. From arrival at the patient's side to administration of the first dose of epinephrine the mean time was 5.0 minutes (95% CI: 4.7 min to 5.4 min) for the IO group and 8.8 minutes (95% CI: 6.6 min to 10.9 min) for the PIV group ($p < 0.001$). In this study the proximal humerus was the site most commonly accessed at 86.2% with a 95.65% first attempt success rate. Authors recommended the use of IO vascular access for time-dependent medical conditions for out-of-hospital situations.⁴⁷

A recent retrospective study by Clemency et al. compared the rates of emergency department (ED) ROSC between IO and peripheral IV (PIV) vascular access in OOHCA. For 788 (60.15%) subjects, EMS providers attempted PIV access first. In 552 (39.85%) subjects IO access was the first method for vascular access. ROSC at time of ED arrival rates were 19.67% for PIV access and 19.92% for IO access. Based on the primary end point ROSC at time of ED arrival, the IO approach was non-inferior to the PIV approach ($p = 0.01$); and IO access had superior first attempt success rates compared to PIV. Investigators noted this study represents evidence supporting the AHA guidelines stating "it is reasonable for providers to establish IO access if IV access is not readily available (Class IIa, LOE C)." Authors noted a limitation of their study was that it did not report on final neurological outcomes for included patients.^{25,48}

Bramlett 2016 also conducted a retrospective study on approximately 800 cases of OOHCA in which they found a significantly greater insertion success rate for IO access but no difference between IO and IV for ROSC or time to first epinephrine.⁴⁹ In a study done in Singapore conducted by Chin et al., the objective was to determine if there would be a difference in rates of vascular access and ROSC if paramedics were able to use IO access after two initial IV attempts failed. Investigators found higher vascular access success and pre-hospital epinephrine administration rates with the addition of IO access but no significant difference for ROSC.⁵⁰ A small hospital study by Lantos 2015 describes data from a 2013 policy change which allowed rapid response team nurses to place IO access for in-hospital cardiac arrests. Prior to the change the mean time to first medication was 4.3 minutes with 53.1% patients surviving to ICU. Post-policy change patients that received IO access had a mean time to medication of 1.7 minutes and 85.7% survival to ICU.⁵¹ An earlier study of 22 patients with OOHCA suggested IO placement was not associated with improved survival for adults in OOHCA.⁵²

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Technique/Training

Note

For comprehensive training information, please refer to the Teleflex web site www.teleflex.com/ezioeducation or contact Customer Service/Clinical Support at **866.479.8500**. For calls outside the US, please dial **+1.866.479.8500**.

How Should the Skin Be Prepared for IO Insertion?

Similar to a peripheral IV site: prior to insertion, the site should be thoroughly cleaned using a clean, non-touch technique with antiseptic solution (commonly referred to as “aseptic”) per your protocol.

Is a Local Anaesthetic Necessary for an EZ-IO Device Insertion in an Alert Patient?

EZ-IO Needle Set insertion does not generally require local soft tissue anaesthesia, but discomfort resulting from the insertion is variable, so local infiltration of an anaesthetic prior to insertion may be done if the clinician desires. However, the rapid flush of saline required after initial insertion is often painful for patients responsive to pain; therefore following the IO needle insertion, anaesthetic (preservative-free and epinephrine-free intravenous lidocaine) delivered slowly through the IO catheter into the medullary space may be considered for use under institutional protocols or policies. In general, the infusion of fluids at normal flow rates does not cause significant pain or discomfort.^{1,2}

For more comprehensive information about lidocaine dosing regimens, please refer to the Teleflex web site: www.eziocomfort.com.

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- 2 Montez D, Puga T, Davlantes C, Philbeck T. IO infusion pain mitigation in the sternum and proximal humerus: Establishing a regimen. *Crit Care Med* 2016; 44(12):154^{TS}

How is the Appropriate EZ-IO Needle Set Length Determined? Can the “Paediatric” Needle Sets be Used in Adults, or “Adult” Needle Sets in Paediatric Patients?

The EZ-IO Needle Sets are based on approximate weight and not classified as “paediatric” or “adult”. The needle sets are 15 gauge and available in three different lengths including 15 mm (for 3 to 39 kg), 25 mm (3 kg or over), and 45 mm (40 kg or over and/or excessive tissue depth). Clinical judgment should be used to determine appropriate needle set selection based on patient anatomy, weight, and tissue depth. For example, a small adult may require a shorter length catheter whereas an obese child may require a longer catheter. The longer 45 mm needle set should be used when there is excessive tissue overlying the insertion site for any patient 40 kg or over, and for the proximal humerus site in most adults.

The EZ-IO Catheter is marked with black lines starting approximately 5 mm from the hub. With *every* insertion, the needle set should be used as a “depth gauge” to measure tissue depth to determine if the needle set is the correct length for the patient prior to powering the needle set (or manually inserting) past the outer cortex and into the medullary space. Indications that the needle set is not long enough include the following: the needle set does not reach bone or no black lines are visible above the skin with the tip of the needle set touching bone. If those conditions occur, the inserter must choose a longer length needle set or re-evaluate the choice of a particular site for insertion. Failure to see at least one black line depth mark is an indication for the clinician that the needle is too short and will not reach the medullary cavity, which may result in inadequate IO access. Using a needle set that is too short will increase the risk of catheter dislodgement; inserting too deeply may breach the opposite cortex. Both situations can potentially lead to infiltration/extravasation.

[See Selection of “Appropriate Insertion Site and Needle Set”, page 21.]

How Deep Should the EZ-IO Needle Set Be Inserted into the Bone?

Push needle set tip through the skin until tip rests against the bone. At least one black line on the catheter must be visible above the skin for confirmation of adequate needle set length (the line helps serve as a “depth gauge” of the soft tissue to the bone). Engage driver trigger and apply gentle-moderate, steady downward pressure until needle set penetrates the bone. Once the needle set is at the desired depth, the trigger is released to avoid continual spinning. The hub of the needle should be close to or flush with (but not pressed into) the skin to prevent undesired pressure on the skin around the insertion site which may cause skin injury.

Paediatrics: Immediately release the trigger when you feel the “pop” or “give” as the needle set enters the medullary space.

Adults: Gently drill into the medullary space until a loss of resistance is felt (approximately 1-2 cm) or until the needle set hub is close to or flush with, but not pressed into, the skin to avoid undesired pressure on the skin around the insertion site. The decreased resistance indicates entry into the medullary space. In the humerus, for most adults a 45 mm needle set should be advanced until catheter hub is flush with the skin.

Clinicians are strongly encouraged to study the training materials and obtain hands-on experience with a Teleflex Arrow EZ-IO Clinician for safe and proper use of the EZ-IO Device. [See Selection of Appropriate Insertion Site and Needle Set, page 21] [See Paediatrics: Newborns, Infants, Children and Adolescents, page 54]

What if the Driver Seems to Be Losing Power and Slows Down?

The most common cause of the driver slowing or stalling is improper technique; specifically, applying too much downward pressure during insertion. The needle set should always be inserted with gentle-moderate pressure, allowing the driver to “do the work” and beveled needle set to cut through the bony cortex as it advances, using the minimal amount of pressure required to keep the driver advancing into the bone. If the driver is unavailable or inoperable, the EZ-IO Needle Set may be inserted manually without the driver as a back-up insertion method. [See Manual Insertion Technique on this page]

If the condition of the driver slowing or stalling persists despite proper use, please call Customer Service at **866.479.8500** (outside US: **+1.866.479.8500**). The drivers are equipped with a power indicator light that illuminates when the driver trigger is deployed. This light illuminates green when the battery has sufficient power and red when the driver needs to be replaced. Multiple factors influence battery life including storage conditions such as temperature extremes, frequency of use, and age of driver. Refer to the driver IFU for more information. [See EZ-IO Driver and Training Driver, page 33]

What is the Manual Insertion Technique When a Driver is Unavailable or Inoperable?

Manual insertion of IO access is recommended only when the driver is unavailable or inoperable. Use of the driver optimises tactile feedback and sensitivity. Clinicians can more easily discern when the needle set passes from the hard outer bone cortex into the less dense medullary space.¹ The mechanised driver creates a clean entry hole the size of the catheter.² See Figure 3.



Figure 3

Steps:

1. Push needle set tip through the skin until tip rests against the bone. At least one black line on the catheter must be visible above the skin for confirmation of adequate needle set length.
2. Hold the needle set with the catheter hub and stylet as one piece (ensuring the stylet and hub remain screwed together).
3. Rotate clockwise/counter-clockwise while applying gentle-moderate, steady downward pressure without rocking the needle set. Allow rotation and pressure to penetrate the bone cortex, not excessive force.
 - **Paediatrics:** Stop insertion when a change in pressure or resistance is felt as a “give” or “pop” indicating entry to medullary space.
 - **Adult:** Advance needle set approximately 1-2 cm after entry into medullary space which is felt as a change in resistance; in the proximal humerus for most adults the needle set should be advanced 2 cm or until hub is flush or against the skin.
4. Stabilise needle set hub and remove stylet.

For additional information see www.teleflex.com/ezioeducation

References:

- 1 Miller L, Philbeck T, Bolleter S, Garcia G. Tactile feedback comparison of three types of intraosseous access devices for needle insertion accuracy. *Ann Emerg Med* 2010;56(3):S133.¹⁸
- 2 Teleflex internal study done in cadaveric bone. Test data may not be indicative of clinical performance.

How Should the EZ-IO Catheter Be Stabilised?

After insertion of the EZ-IO Catheter, use the EZ-Stabilizer Dressing to help secure the catheter and help prevent accidental dislodgement. Remove the stylet holding the catheter hub in place, place EZ-Stabilizer Dressing over the hub, then attach the primed EZ-Connect Extension Set to the hub. Firmly secure EZ-Connect Extension Set by twisting clockwise. If an EZ-Stabilizer dressing is unavailable, other methods should be used to secure the device. Additionally, for the proximal humerus site, the arm should be secured in an adducted position to minimise chance of dislodgement; and in paediatric patients, a leg board or other securement method may be needed to prevent dislodgement due to movement. [Refer to “EZ-Stabilizer Dressing Directions for Use” at www.teleflex.com]

Should the EZ-Connect Be Primed with Fluid Prior to Use?

Yes. Always prime the EZ-Connect Extension Set with fluid before attaching to the EZ-IO Catheter hub. The approximate volume of the EZ-Connect Extension Set is 1.0 ml.

Does the EZ-Connect Extension Set Meet Hospital Infection Control Standards?

The EZ-Connect Extension Set uses the Robertsite Needleless Connector by Halkey-Roberts. The connector valve satisfies all Centers for Disease Control and Prevention (CDC) requirements for needleless intravascular systems. For further specification information see: <http://www.halkeyroberts.com/userfiles/files/Medical%20Miscellaneous/RNV%20Book/RNV%20Book%202015.pdf> (Accessed 02/08/2017) [See EZ-Connect Extension Set, page 35]

What is the EZ-IO Needle Set Made of?

The catheter and stylet are made of 304 stainless steel. The plastic hub is medical grade polycarbonate. The EZ-IO Needle Set is not made with natural rubber latex.

Is a Syringe Flush Necessary after IO Insertion?

Yes. It is essential to inject a syringe flush into the IO space before attempting to infuse fluids through the IO catheter. A syringe flush helps clear the marrow and fibrin from the medullary space, allowing for effective infusion rates.

NO FLUSH = NO FLOW.

In paediatric patients, flush with 2–5 mL of normal saline; in adult patients, flush with 5–10 mL of normal saline.

Do **NOT** use extreme pressure for the flush, especially in paediatric patients, as it may increase the risk of extravasation/infiltration and cause more pain for the patient.

[See Flow Rates and Infusion Under Pressure, page 20]

Is it Necessary to Flush the IO Line with Saline after Infusing Medications Via the IO Route?

Yes. As with an IV infusion, patency should be confirmed and the IO line should be flushed before and after infusion to ensure all prescribed medication has entered the vascular space in the proper amount and concentration. The volume of the EZ-Connect Extension Set is approximately 1.0 ml and should be factored in for medication administration.

What Flow Rates Can Be Achieved With Intraosseous Vascular Access? How Can Flow Rates Be Optimised?

In published literature, IO flow rates (delivered under pressure) range from 200 ml/hr to 9,900 ml/hr.¹⁻⁶ A 2010 estimate for flow rates in adults (based on a human volunteer study) approximated five liters per hour through the humerus and one liter per hour through the tibia; both with 300 mmHg of pressure.⁴ A more recent volunteer study resulted in proximal humerus mean flow rates of 6,292±3,277 ml/hr (n=52); sternal flow rates were 9,587±2,706 ml/hr (n=27).⁶ As with other vascular access lines, IO flow rates will vary among patients and anatomical sites.

Adequate flow rates are dependent on correct insertion depth, performing a syringe flush prior to IO infusion, and infusing fluids and medications under pressure (e.g. infusion pressure pump or pressure bag). Gravity alone will rarely generate adequate flow rates; the higher the pressure, the faster the flow.⁶⁰ In general, research shows that higher flow rates are obtainable in the proximal humerus and sternal sites than tibial sites.⁴⁻⁶

[See Flow Rates and Infusion Under Pressure, page 20]

Does the Syringe Flush Have to Be Repeated With Prolonged Use? Will the IO Catheter Become Occluded if Unused for a Few Hours?

IO access may be compromised if the line is not used for prolonged periods. Often, IO lines can be opened by an additional syringe flush. In an ongoing clinical adult volunteer study, an infusion rate of 30 ml/hour per infusion pump has been sufficient to maintain IO line patency for a period of 48 hours.⁷

Can a Heparin Lock/Saline Lock Be Used to Maintain Patency of an IO Line? What Should Be Done if the Line Clots?

There is no data on the practice of using a heparin or saline lock solution with IO vascular access. Confirm IO catheter placement in the medullary cavity. Attempt to administer a syringe flush to open the line. Depending on frequency of IO site access, a repeat syringe flush may be necessary to re-open the line. Organisational policies and procedures should dictate whether instillation of medications should be used to open an obstructed IO catheter.

Can Another IO Catheter Be Placed in the Same Bone Immediately Following a Failed Insertion or Infusion?

No, this is a contraindication for use for the EZ-IO Needle Set. After a failed insertion (or once an IO catheter is removed), another IO catheter placement should not be attempted in the same bone for 48 hours. If multiple attempts are made in the same bone, repeated penetration of the cortex will likely result in infiltration or extravasation, which may lead to more serious complications (e.g. compartment syndrome). An alternate site must be chosen.

What is Proper EZ-IO Catheter Removal Technique?

To withdraw the catheter, remove the EZ-Connect Extension Set and EZ-Stabilizer dressing. Attach a Luer Lock syringe to the hub. Maintaining axial alignment, twist the syringe and catheter clockwise, while pulling straight out. **Do not rock or bend the catheter during removal.** Dispose of all sharps in a proper sharps container. Apply pressure as needed, dress the site. Refer to company training materials and Instructions for Use (IFU) for proper removal technique.

What Can Be Done if the EZ-IO Catheter Breaks Off the Hub or is Impossible to Remove by the Recommended Method?

If the plastic hub breaks from the catheter, grasp the catheter with a haemostat, Kelly clamp, or similar medical tool using aseptic technique and rotate the catheter while firmly pulling outward. If the catheter cannot be visualised, a physician should be consulted. Refer to company training materials and IFU for proper removal technique.

Does the Insertion Site Leak after EZ-IO Catheter Removal?

A small amount of bleeding may occur after EZ-IO Catheter removal. Apply direct pressure to the site for 1-2 minutes to control bleeding. More time may be required for anticoagulated patients or patients with coagulopathy.

Does the Insertion Site Require Special Dressing or Care after Device Removal?

No special dressing is required after removal of the EZ-IO Catheter. A bandage or any clean dressing is appropriate. Post IO catheter removal, monitor the involved limb for any signs of delayed presentation of symptoms of potential complications including but not limited to fever, discoloration, swelling, pain (with active or passive motion), paraesthesias, skin feeling cool or warm, pulses, firmness or taut feel to area as compared to other limb.

Discharge instructions should include teaching patient/family members to assess for and seek immediate treatment for development of any of the above symptoms.

Can a Patient Ambulate With a Tibial IO Catheter in Place?

Ambulation should be discouraged until the tibial IO catheter is removed to reduce risk of dislodgement.

Are There any Exercise Restrictions after EZ-IO Catheter Removal?

No. There are generally no exercise restrictions after removal of an EZ-IO Catheter unless the physician otherwise instructs to limit activity.

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Flow Rates and Infusion Under Pressure

Flushing and Flow Rates

Described in published literature, IO flow rates (delivered under pressure) range from 200 mL/hr to 9,900 mL/hr.¹⁻⁶ A 2010 estimate for flow rates in adults (based on a human volunteer study) approximated five liters per hour through the humerus and one liter per hour through the tibia; both with 300 mmHg of pressure.² A more recent volunteer study resulted in proximal humerus mean flow rates of $6,292 \pm 3,277$ mL/hr (n=52); sternal flow rates were $9,587 \pm 2,706$ mL/hr (n=27).⁶ As with other vascular access lines, IO flow rates will vary among patients and anatomical sites. Flow rates are dependent on performing a syringe flush prior to IO infusion and infusing fluids and medications under pressure. Failure to perform a syringe flush is a common reason for lack of flow and/or inadequate flow rates. Other factors affecting IO flow rates include bone structure, catheter position within bone, types of fluids being infused, and specific patient characteristics.

Infusing Under Pressure

An IV pressure bag capable of generating 300 mmHg pressure or a standard IV infusion pump is usually required. To infuse fluids into the IO space one must first overcome the intrinsic resistance of the pressure gradient between the IO space and the infusion system.⁷ Sufficient pressure and consistent flow rate usually cannot be attained by manually squeezing the IV bag.⁶⁰

Pressure Pumps

Pressure is a rate-limiting factor in achieving adequate flow rates in IO infusions; the higher the pressure, the greater the flow rate. Some electronic infusion pumps are designed to administer large volumes of fluid rapidly, but often work by measuring volume rather than infusion pressure. Some rapid infusers (such as the Level 1) are set to deliver a constant 300 mmHg of pressure and will deliver the volume achievable with that set pressure.⁸ When pressure exceeds 300 mmHg most infusion pumps, including rapid infusers, automatically shut off or deliver the last rate achieved prior to the excessive pressure. Therefore, these pumps may limit the ability to deliver desired IO flow rates due to limits on infusion pressures. If adequate IO flow rates cannot be achieved with an infusion pump, a simple pressure bag may be used.

Maximum Pressures for Infusion

In clinical practice, a maximum of 300 mmHg is generally used to facilitate flow. Therefore, there is no known “maximum” infusion pressure. There are several considerations:

- **Equipment limits.** Most pressure bag infusion systems will not exceed 300 mmHg.
- **Flow rates.** Pressure and flow rates are directly correlated: greater applied pressure will generally result in higher flow rates.²
- **Pain management.** Pressure and infusion pain are directly correlated; therefore, higher pressures will generally result in higher pain in the conscious patient, and a greater need for pain management.²
- **Potential for bone damage.** It is unknown whether higher infusion pressures have potential for medullary damage.

A preclinical study by Lairet resulted in two instances of a distal extraosseal leak of unknown cause (thought to be clinically insignificant) with the use of the higher pressures (approximately 600 mmHg) of the power injector. However, subsequent histological evaluations showed no damage in the limbs that received power-infused contrast media (under high pressure).⁹ Another preclinical study conducted to examine the immediate effects of power injection of contrast media on the medullary cavity and marrow in mature swine found no histological difference between the limbs that received power injection and those that did not, when examined post-infusion.¹⁰

High Pressure Infusions/Power Injection

The EZ-IO Catheter has been shown to withstand up to 325 psi (approximately 16,800 mmHg) without catheter leakage or rupture in an engineering study.¹¹ In another study, the EZ-Connect Extension Set did not withstand this level of pressure and should not be used for high pressure infusion/power injection.¹² The EZ-IO Catheter has not been rated for power infusion.

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Selection of Appropriate Insertion Site and Needle Set

IO site selection depends on patient age, size, anatomy, presenting condition; as well as ability to locate anatomical landmarks, and clinical judgment and experience. Site selection is also dependent on the absence of contraindications, accessibility of the site, and the ability to monitor and secure the site. Comparative studies in the literature may also help guide decision-making. Several clinical and preclinical studies suggest the humerus may be a superior extremity access site for flow rates, drug delivery, and management of infusion pain, although Ong’s clinical study reported no significant difference in flow rates between the tibia and humerus.¹⁻⁵ Regardless of IO site selected the clinical patient scenario, clinician experience and comfort level must be taken into consideration.

Abdominal/Lower Extremity Trauma: The preferred IO sites for fluid and drug administration in patients with lower extremity, abdominal or pelvic injuries are the proximal humerus and sternum.⁶⁰ Fluids given rapidly reach the central circulation via the superior vena cava, thereby bypassing pelvic and abdominal vasculature.^{2,4,6} In cases of major trauma to a lower extremity with suspected vascular injury, IO access should not be attempted in that extremity.

EZ-IO Needle Set Selection

Clinical judgment should always be used to determine appropriate needle set selection based on patient anatomy, weight, tissue depth, and presenting condition. The EZ-IO Needle Set is 15 gauge and is available in three different lengths with associated weight ranges to serve as a general

guide: 15 mm (pink hub, 3-39 kg weight range), 25 mm (blue hub, 3 kg or over), and 45 mm (yellow hub, 40 kg or over and/or excessive soft tissue). Tissue depth over the insertion site should always be assessed when determining the most appropriate needle set length and prior to every insertion using the EZ-IO Device. *Please note that EZ-IO Needles with red hubs are non-sterile and for non-clinical training purposes only.

The EZ-IO Catheter is marked with black lines. If the EZ-IO Needle Set is inserted through the soft tissue and does not reach the bone, or at least one black mark is visible above the skin when the needle tip is touching the bone, but before power is applied to the driver, a longer needle set or alternate site should be chosen prior to penetration of the cortex. If there is any chance the cortex has been breached, you must choose another target bone to decrease extravasation risk. Clinical experience with the device will ultimately present a more rapid approach to needle set selection, but the black depth line will help to establish if the needle set is long enough and assist in decisions about which needle set length is appropriate for the patient.

Kehrl et al. published a study in 2016 using ultrasound to measure soft tissue depth at the proximal tibia (PT), distal tibia, and proximal humerus (PH) in 75 obese patients with a BMI greater than 30; also assessing whether the tibial tuberosity (TT) was palpable or not palpable in this group. In 70 patients with an average BMI of 45.7, the TT was palpable; and non-palpable in five patients with an average BMI of 67.2. The soft tissue depth exceeded 20 mm at all three anatomic IO sites in all patients with a non-palpable TT. While authors found BMI to be moderately predictive of soft tissue depth, it did not correlate for the higher BMI nor the proximal humerus. The findings suggested a 25 mm needle set would be adequate in the PT for most obese patients with a palpable TT, and the 45 mm needle set should always be used for the PHIO site.⁸

In 2012 Rush et al. reported on a retrospective study in which 50 consecutive MRI images of the humerus were evaluated for the purpose of determining the optimal needle length necessary for successful proximal humerus IO insertion. Results showed the cortical thickness was 4 mm in all cases and that an IO needle length ranging between 40-50 mm should be used via the anterior approach.⁹

Adults: Generally the 25 mm EZ-IO 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/or any site when excessive tissue overlies the insertion site. Visualisation of at least one black line on the catheter, above the skin, when the needle tip is touching bone must still be done prior to every insertion.

Paediatrics: The following is a general guide for needle set selection in paediatric patients (3-39 kg). **Note:** visualisation of at least one black line on the catheter, above the skin, when the needle tip is touching bone must still be done prior to every insertion:

15 mm: Proximal and distal tibia insertion in neonates and small infants.

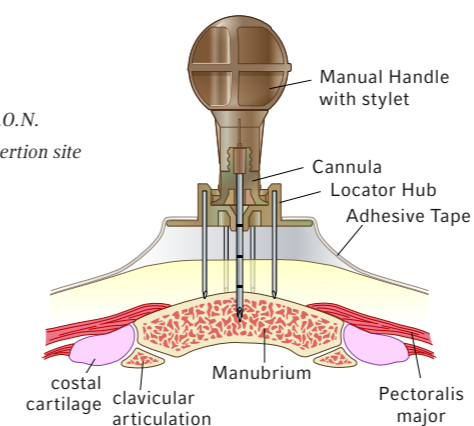
25 mm: Distal femur insertion in neonates and small infants or proximal humerus, distal femur, proximal, and distal tibia insertion in children.

References:

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Figure 5

Drawing of EZ-IO T.A.L.O.N. Sternal Locator over insertion site (the manubrium)



Sternal Site

First described by Tocantins in 1940, the sternum was among the first bones used for IO access.¹ This site option is important when other sites are contraindicated, as with injuries sustained due to explosives when the manubrium of the sternum may be the most accessible uninjured site or in tactical medicine due to body armor. The EZ-IO T.A.L.O.N. Needle Set is indicated for military and tactical team use. The EZ-IO T.A.L.O.N. Needle Set provides seven site options with access to the sternum using a sternal locator; and using the needle set without the locator and manual insertion technique, gains access to the proximal humerus, proximal tibia, and distal tibia. In a clinical volunteer study Philbeck et al. described mean sternal flow rates ranging from 1,130 ± 692 mL/hr with gravity and no pressure to 5,327 ± 1,724 mL/hr with 300 mmHg of pressure.² A more recent human volunteer study resulted in sternal flow rates when using the EZ-IO T.A.L.O.N. Needle Set and 300 mmHg of pressure of 9,587 ± 2,706 mL/hr (n=27).³ Cadaveric studies using the FAST1 (PYNG Medical†, Richmond, Canada) have reported a mean sternal flow rate of 93.7 ± 37.9 mL/min.⁴ (*PYNG Medical was acquired by Teleflex on April 3, 2017)

Figure 4

EZ-IO T.A.L.O.N. Sternal Locator application area

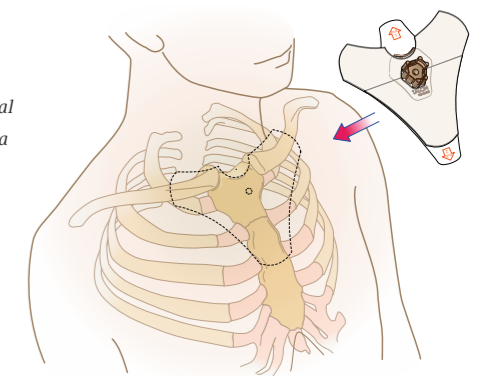
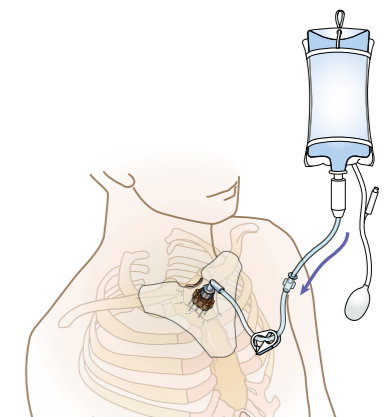


Figure 6

EZ-IO T.A.L.O.N. sternal insertion with fluid infusion and pressure bag



Proximal Humerus

For adult patients, studies support the proximal humerus as an efficacious IO site for insertion success, flow rates, drug delivery, and management of infusion pain. Philbeck 2010 describes a comparative study with the proximal humerus as having superior flow rates and less pain when compared with the tibia.⁵⁻⁹ One of the first descriptions of humeral IO access use was published in 2009 in the *Journal of Trauma*. The study compared various vascular access methods including proximal humerus IO, peripheral venous access, and central venous access routes. The study concluded that access into the proximal humerus was significantly faster than the other two routes.¹⁰ Three prehospital studies have evaluated use of the proximal humerus for cardiac arrest.

The most recent retrospective study by Ross 2016 reported on 2,600 cases of IO access for cardiac arrest with a total first pass success rate of 95.6% and the majority placed in the humerus (86.2% placed in the proximal humerus and 13.8% in the proximal tibia). The humerus had a significantly lower complication rate when compared to the tibia 8.2% versus 12.6% (p<0.01).¹¹ Two prehospital studies by Reades et al. found the proximal humerus to have a lower success rate than the proximal tibia.^{12,13} Lack of stabilisation, as described in this article, may have contributed to dislodgements and the lower success rates. Wampler et al. reported a success rate of 94%.

EMS providers participated in a standardised training programme provided by EZ-IO Clinician Educators guiding proper landmarking, needle selection, and the importance of catheter and limb securement prior to the start of the study.⁶

Drug Delivery

In a study with healthy adult volunteers, contrast media injected through the proximal humerus site, and captured under fluoroscopy as it entered the right atrium took 2.42 seconds (mean time).¹⁴

A preclinical study in 2006 using epinephrine demonstrated that humeral IO access generated higher mean arterial pressures than central venous access. The authors concluded IO humeral head delivery of epinephrine during cardiac arrest is as effective as intravenous infusion.¹⁵ A 2007 study in swine compared the proximal humerus and sternal routes during CPR, and concluded the humerus route is an effective alternative to IO sternal delivery during CPR.¹⁶

Flow Rates

Clinical and healthy volunteer studies have evaluated flow rates using various sites and pressure methods. With the exception of one study by Ong et al., evidence to date supports the proximal humerus and sternum as the optimal sites when maximum flow rates are desired.^{2,3,8,9}

Pain Management

A series of studies in healthy volunteers demonstrated reasonable relief of IO infusion pain with initial preservative-free and epinephrine-free lidocaine (safe for intravenous use) dosages of 40 mg, and a subsequent 20 mg dose after flushing.⁹ For IO infusions in the proximal humerus, pain relief was sustained for 90 minutes without re-dosing. The proximal humerus may be the preferred site for conscious patients due to less infusion pain and the ability to better manage pain as compared to the proximal tibia. A volunteer study done in June 2016 administering 2% preservative-free and epinephrine-free lidocaine compared doses of 40 mg followed by a flush followed by placebo or an additional 20 mg dose. Conclusion of this study states: "Infusion pain through a PH IO may be managed with a single 40 mg lidocaine prior to infusion, but a total of 60 mg may be considered for sternal IO infusion." Results state that the mean pain score was statistically different between a 40 mg dose vs a 60 mg dose but that this was not shown clinically.

Lidocaine and appropriate dosages must be prescribed by a qualified prescriber. More information on pain management is available at www.eziocomfort.com.

Can the Proximal Humerus Site Be Used in the Perioperative Setting?

When indicated for use in the perioperative setting, the EZ-IO Catheter should be inserted into the proximal humerus as described in the instructions for use. After placement, the patient's arm can be repositioned as needed but extreme care should be taken to ensure the arm is not abducted more than 45 degrees from the side of the body. Specific training is available for proximal humerus insertion site identification including literature with step-by-step instructions, anatomic visuals, written training materials, and video demonstrations. This information is available at: <http://www.teleflex.com/ezioeducation>.

When accessing the humerus site, the following should be considered:

- **Needle Set Selection.** The proximal humerus is covered by layers of muscle and skin. Therefore, the longer EZ-IO 45 mm Needle Set (yellow hub) is recommended for this site in most adult patients or adolescents 40 kg or over. Clinical judgment should be used for needle set selection in paediatric patients, taking into account the weight of the patient, and the overlaying tissue depth.
- **Site Identification.** Identification of the correct insertion site is a critical aspect of accessing the proximal humerus. The surgical neck and the greater tubercle of the proximal humerus are key landmarks.

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EZ-IO Device Proximal Humerus Identification and Insertion Technique

Identify the Proximal Humerus:

Figure 7

Place the patient's hand over the abdomen (if unable to place as pictured ensure the elbow is adducted and humerus internally rotated).



Figure 8

Place your palm on the patient's shoulder anteriorly.

- The area that feels like a "ball" under your palm is the general target area.
- You should be able to feel this ball, even on obese patients, by pushing deeply.



Figure 9

Place the ulnar aspect of one hand vertically over the axilla.

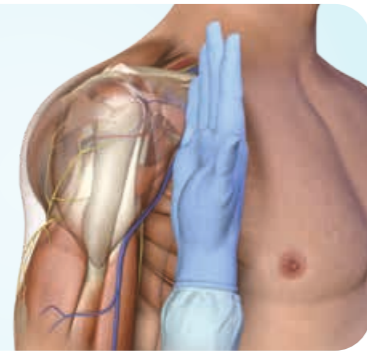


Figure 10

Place the ulnar aspect of the opposite hand along the midline of the upper arm laterally.

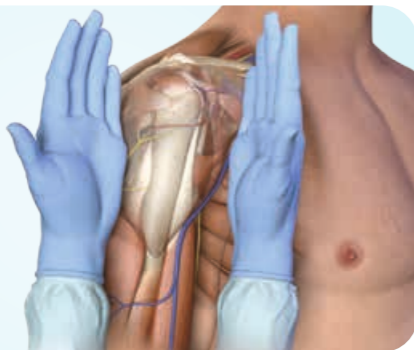


Figure 11

Place your thumbs together over the arm.

- This identifies the vertical line of insertion on the proximal humerus.



Figure 12

Palpate deeply as you climb up the humerus to the surgical neck.

- It will feel like a golf ball on a tee – the spot where the "ball" meets the "tee" is the surgical neck.
- The insertion site is on the most prominent aspect of the greater tubercle, 1 to 2 cm above the surgical neck.

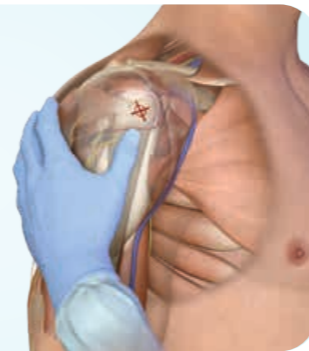
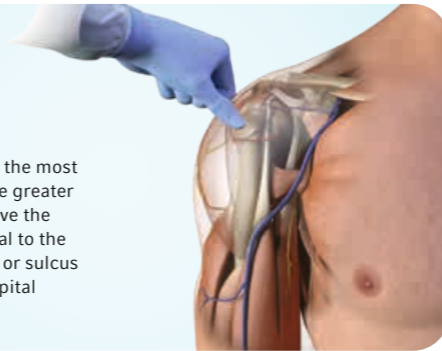


Figure 13

The insertion site is on the most prominent aspect of the greater tubercle, 1 to 2 cm above the surgical neck and lateral to the intertubercular groove or sulcus (also known as the bicipital groove).



Insertion:

- Prepare the site by using antiseptic solution per institutional protocol using a clean, aseptic technique.
- Attach Needle Set to EZ-IO Power Driver and remove Safety Cap from Catheter.
- Once the insertion site is determined as described above, insert the needle set tip through the skin approximately 45 degrees anterior to the horizontal plane and aim the needle set downward approximately 45 degrees. Some find it helpful to think of aiming toward the inferolateral border of the scapula. See Figure 14.
- Push the needle set tip through the skin until the tip touches the bone.

IMPORTANT: At least one black line from the hub must be visible above the skin for confirmation of adequate needle length (always check this before pressing the trigger).

- Gently drill into the humerus 2 cm or until the hub reaches the skin in an adult. **Stop when you feel the "pop" or "give" in infants and children.** Avoid recoil by actively releasing the trigger when you feel the needle set enter the medullary space – do **NOT** pull back on the driver when releasing the trigger.

Figure 14

Insert the needle set tip over the anterolateral part of the arm, 1-2 cm above the surgical neck, then aim the needle set downward at approximately a 45-degree angle, aiming toward the inferolateral border of the scapula.



Figure 15

Hold the hub in place and pull the driver straight off.



Figure 16

- Continue to hold the hub while twisting the stylet off the hub with anticlockwise rotations. The needle should feel firmly seated in the bone (first confirmation of placement).
- Place the stylet in a sharps container.



Figure 17

Place the EZ-Stabilizer Dressing over the hub.



Figure 18

- Attach a primed EZ-Connect Extension Set to the hub, firmly secure by twisting clockwise.
- Pull the tabs off the EZ-Stabilizer Dressing to expose the adhesive, apply to the skin.



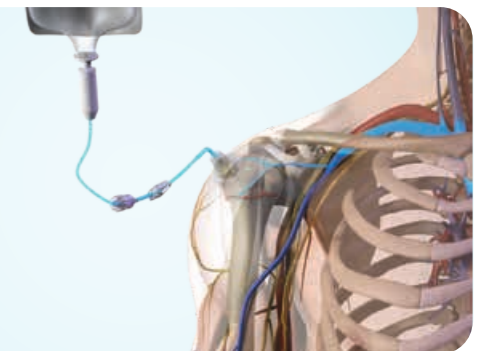
Figure 19

Aspirate for blood/bone marrow (Second confirmation of placement. The inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after the flush.).



- Flush the IO catheter with normal saline (5–10 ml adults; 2–5 ml for infants and small children).
- Connect fluids if ordered; infusion may need to be pressurized to achieve desired rate. See Figure 20.
- Secure the arm in place across the abdomen, or in adducted position (with the patient's arm at his/her side). Monitor infusion, site and limb frequently.

Figure 20

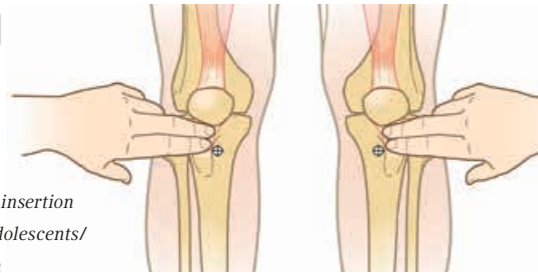


Proximal Tibia

Proximal Tibia Insertion Site Identification – Adults/Adolescents/Larger Children

Extend the leg. Insertion site is approximately 2 cm medial to the tibial tuberosity, or approximately 3 cm below the patella and approximately 2 cm medial, along the flat aspect of the tibia. See Figure 21.

Figure 21

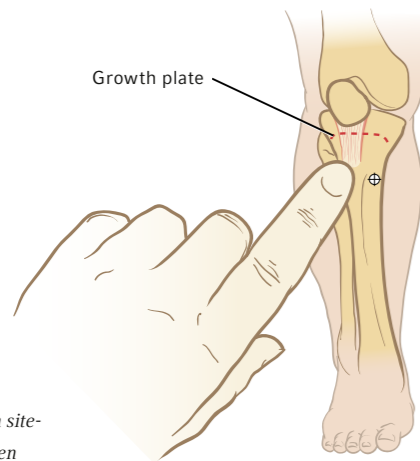


Proximal tibia insertion site – adults/adolescents/larger children

Proximal Tibia Insertion Site Identification – Neonates/Infants/Children

Neonates, infants and small children: Extend the leg. Insertion site is approximately 1 cm medial to the tibial tuberosity, or (if the tibial tuberosity cannot be palpated) approximately 1 cm medial to the tibial tuberosity, or just below the inferior border of the patella (approximately 1 cm) and slightly medial (approximately 1 cm) along the flat aspect of the tibia. Pinch the tibia between your fingers to identify the medial and lateral borders, and insert in the center of the bone. See Figure 22.

Figure 22



Proximal tibia insertion site- neonates/infants/children

EZ-IO Device Proximal Tibia Insertion Technique:

Prepare the site with antiseptic as per institutional protocol. Use a clean aseptic technique.

1. Attach Needle Set to EZ-IO Power Driver and remove Safety Cap from Catheter.
2. Stabilise the extremity.
3. Aim the needle set tip at a 90-degree angle to the flat surface of the bone.
4. Push the needle tip through the skin until the tip touches the bone.

IMPORTANT: At least one black line on the catheter *must* be visible above the skin for confirmation of adequate needle set length (check for this before pressing the trigger).

5. Gently drill, advancing the needle set approximately 1–2 cm after entry into the medullary space (felt as a loss of resistance) or until the needle set hub is close to the skin in adult patients.

Infants and small children: Gently drill, immediately stop advancing and release the trigger when you feel the “pop” or “give” as the needle set enters the medullary space.

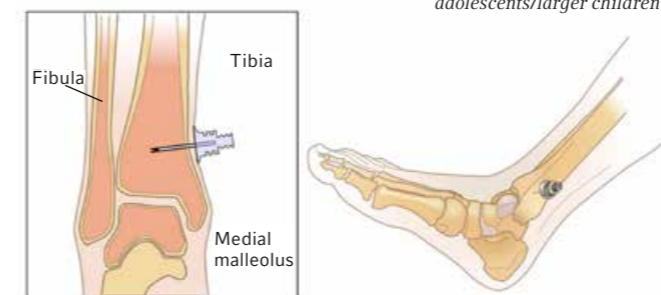
- Do **NOT** pull/jerk back (recoil) on the driver when releasing the trigger.
6. Hold the hub in place and pull the driver straight off needle set.
 7. Continue to hold the hub while twisting the stylet off the hub with anticlockwise rotations.
 8. The catheter should feel firmly seated in the bone (first confirmation of placement).
 - Place the stylet in a sharps container.
 9. Place the EZ-Stabilizer dressing over the hub.
 10. Attach a primed EZ-Connect Extension Set to the hub, firmly secure by twisting clockwise.
 11. Pull the tabs off the EZ-Stabilizer Dressing to expose the adhesive, apply to the skin.
 12. Aspirate for blood/bone marrow (Second confirmation of placement. The inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after the flush.).
 13. Flush the IO catheter with normal saline (5-10 ml adults; 2-5 ml for infants and small children).
 14. Connect fluids if ordered, infusion may need to be pressurized to achieve desired rate.
 15. Monitor infusion, site, and limb frequently.

Distal Tibia

Distal Tibia Insertion Site Identification – Adults/Adolescents/Larger Children

Insertion site is located approximately 3 cm proximal to the most prominent aspect of the medial malleolus. Palpate the anterior and posterior borders of the tibia to assure that your insertion site is in the flat center of the bone and 90 degrees (or perpendicular) to the surface of the bone. See Figure 23.

Figure 23

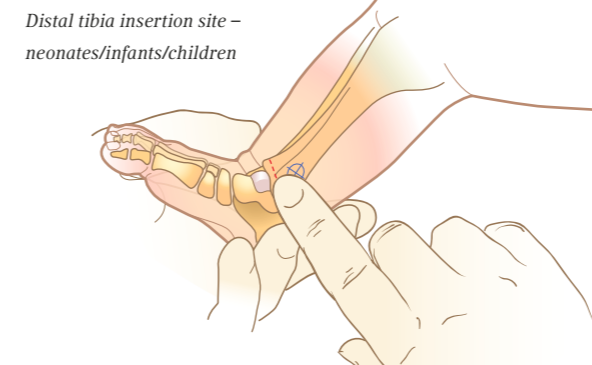


Distal tibia insertion site – adults/adolescents/larger children

Distal Tibia Insertion Site Identification – Neonates/Infants/Children

Insertion site is located approximately 1-2 cm proximal to the most prominent aspect of the medial malleolus. Palpate the anterior and posterior borders of the tibia to assure that your insertion site is in the flat center of the bone and 90 degrees to the surface of the bone. See Figure 24.

Figure 24



Distal tibia insertion site – neonates/infants/children

EZ-IO Device Distal Tibia Insertion Technique:

Prepare the site with antiseptic as per institutional protocol. Use a clean aseptic technique.

1. Attach Needle Set to EZ-IO Power Driver and remove Safety Cap from Catheter.
2. Stabilise the extremity.
3. Aim the needle set tip at a 90 degree angle to the flat surface of the bone.
4. Push the needle tip through the skin until the tip touches the bone.

IMPORTANT: At least one black line on the catheter *must* be visible above the skin for confirmation of adequate needle set length (check for this before pressing the trigger).

5. Gently drill, advancing the needle set approximately 1-2 cm after entry into the medullary space (felt as a loss of resistance) or until the needle set hub is close to the skin in adult patients.

Infants and small children: Gently drill, immediately stop advancing and release the trigger when you feel the “pop” or “give” as the needle set enters the medullary space.

- Do **NOT** pull/jerk back (recoil) on the driver when releasing the trigger.
6. Hold the hub in place and pull the driver straight off needle set.
 7. Continue to hold the hub while twisting the stylet off the hub with anticlockwise rotations.
 8. The catheter should feel firmly seated in the bone (first confirmation of placement).
 - Place the stylet in a sharps container.
 9. Place the EZ-Stabilizer Dressing over the hub.
 10. Attach a primed EZ-Connect Extension Set to the hub, firmly secure by twisting clockwise.
 11. Pull the tabs off the EZ-Stabilizer dressing to expose the adhesive, apply to the skin.
 12. Aspirate for blood/bone marrow (Second confirmation of placement. The inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after the flush.).
 13. Flush the IO catheter with normal saline (5-10 ml adults; 2–5 ml for infants and small children).
 14. Connect fluids if ordered, infusion may need to be pressurized to achieve desired rate.
 15. Monitor infusion, site, and limb frequently.

For patients > 12 years old use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

Distal Femur

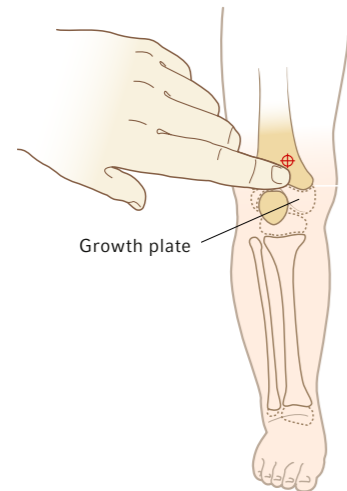
The EZ-IO Device distal femur site is indicated for paediatric patients.

Distal Femur Insertion Site Identification Neonates/Infants/Children

Secure site with leg outstretched to ensure knee does not bend. Identify the patella by palpation. The insertion site is just proximal to the superior border of the patella (maximum 1-2 cm) and approximately 1-2 cm medial to the midline.

See Figure 25.

Figure 25



Distal femur insertion site –
neonates/infants/children

EZ-IO Device Distal Femur Insertion Technique:

Prepare the site with antiseptic as per institutional protocol.

- Use a clean aseptic technique.
- 1. Attach Needle Set to EZ-IO Power Driver and remove Safety Cap from Catheter.
- 2. Stabilise the extremity and secure site with leg outstretched to ensure knee does not bend (to avoid dislodgement after insertion).
- 3. Aim the needle set tip at a 90-degree angle to the center of the bone.
- 4. Push the needle tip through the skin until the tip touches the bone.
 - IMPORTANT:** At least one black line on the catheter must be visible above the skin for confirmation of adequate needle set length (check for this before pressing the trigger).
- 5. Gently drill, immediately stop advancing and release the trigger when you feel the “pop” or “give” as the needle set enters the medullary space.
 - Do **NOT** pull/jerk back (recoil) on the driver when releasing the trigger.
- 6. Hold the hub in place and pull the driver straight off needle set.
- 7. Continue to hold the hub while twisting the stylet off the hub with anticlockwise rotations.
- 8. The catheter should feel firmly seated in the bone (first confirmation of placement).
 - Place the stylet in a sharps container.
- 9. Place the EZ-Stabilizer Dressing over the hub.
- 10. Attach a primed EZ-Connect Extension Set to the hub, firmly secure by twisting clockwise.
- 11. Pull the tabs off the EZ-Stabilizer dressing to expose the adhesive, apply to the skin.
- 12. Aspirate for blood/bone marrow (Second confirmation of placement. The inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after the flush.).
- 13. Flush the IO catheter with normal saline (2-5 ml for infants and small children).
- 14. Connect fluids if ordered, infusion may need to be pressurised to achieve desired rate.
- 15. Monitor infusion, site, and limb frequently.

Care and Maintenance of the EZ-IO Catheter

Care and maintenance of the EZ-IO Catheter is similar to other venous access routes: confirming placement prior to medication administration, maintaining catheter patency, monitoring the insertion site and limb for signs of extravasation/infiltration, or other abnormalities and appropriate device stabilisation and removal. The EZ-IO Device is indicated to remain in place for up to 24 hours in the non-CE indicated markets and for up to 72 hours in the CE-indicated markets.

Confirming EZ-IO Catheter Placement

Prior to administration of medications or fluids, confirm EZ-IO Catheter placement with the following methods:

- Ability to aspirate blood or marrow (an inability to aspirate is sometimes described after initial IO catheter insertion). The inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after the flush.
- Stability of catheter
- Adequate flow rate

EZ-IO Catheter Patency

Depending on the duration of IO site access and infusion rate, a repeat syringe flush may be necessary to reopen the line. Refer to organisational policies and procedures to determine whether instillation of medications should be used to open an occluded IO catheter. One adult volunteer study has demonstrated that a slow continuous infusion rate of 30 ml/hr maintained patency for 48 hours.¹

Pain Management in Conscious Patients (Responsive to Pain)

The pain associated with IO insertion is variable, whereas pain associated with IO infusion under pressure is often severe.² Two percent (2%)* intravenous, preservative-free and epinephrine-free lidocaine has been shown to be effective in limiting or alleviating IO infusion pain. Duration of the anaesthetic effect will vary among patients. Repeat doses of lidocaine may be necessary to maintain anaesthetic effect. Consider systemic analgesia for patients as needed.^{3,4}

* 2% preservative-free and epinephrine-free lidocaine may not be available globally; refer to total dose in milligrams.

One series of studies in healthy volunteers measured the duration of pain relief during IO infusion in the proximal humerus and proximal tibia. During the 90-minute observation period in the tibial study, eight of the volunteers who had previously received 100 mg lidocaine required an additional 20 mg lidocaine to keep the IO infusion pain level below five (on a scale of 0-10). No volunteers in the humeral study, who had previously received 60 mg lidocaine, required additional lidocaine dosing to keep pain levels below five.³ A 2015 abstract noted that the use of additional analgesics may be an effective alternative to lidocaine alone and mitigate the need for repeat lidocaine dosing.⁴ A volunteer study conducted in 2016 compared doses of 40 mg followed by a flush, followed by placebo or an additional 20 mg dose, in the sternum and proximal humerus sites. Conclusion of this study states: "Infusion pain through a PH IO may be managed with a single 40 mg lidocaine prior to infusion, but a total of 60 mg may be considered for sternal IO infusion." Results state that the mean pain score was statistically different between a 40 mg dose vs a 60 mg dose but that this was not shown clinically.

Lidocaine and appropriate dosages must be prescribed by a physician or qualified prescriber. [See Pain Management for IO Infusion, page 51]

Disclaimer

The use of any medication, including lidocaine, given IV or IO is the responsibility of the treating physician, medical director or qualified prescriber and not an official recommendation of Teleflex Incorporated and its subsidiaries. Teleflex is not the manufacturer of lidocaine, and the user should be familiar with the manufacturer's instructions or directions for use for all indications, side-effects, contraindications, precautions and warnings of lidocaine. Teleflex disclaims all liability for the use, application or interpretation of the use of this information in the medical treatment of any patient. Lidocaine dosing recommendations were developed based on research; for additional information, please visit www.eziocomfort.com.

Site Maintenance/Monitoring

Extravasation or infiltration is the most common complication associated with IO insertion and can lead to serious complications such as compartment syndrome and soft tissue necrosis. The IO insertion site should be monitored frequently for any signs of extravasation/ infiltration, localised inflammation, or dislodgement, particularly in the first 10 to 15 minutes after

insertion, anytime the IO catheter is manipulated, and during infusion of vasopressors, vesicants, and with high infusion rates, but at least hourly during all infusions. Specific serial monitoring of the involved limb and IO infusion for any symptoms of potential complications includes, but is not limited to, fever, a decreased flow rate or alarm on infusion pumps, change in patient response to medications, limb discoloration, swelling (this may include serial circumferential measurements for obese or patients with chronic edema), pain (with active or passive motion), paraesthesias, skin feeling cool or warm, pulses, firmness or taut feel to all areas of limb as compared to other limb and/or previous assessments. Ultrasound confirmation of placement may also be helpful as an adjunct to physical examination.^{7,8} Organisational policy should dictate care of the insertion site.

Patient Activity

Ambulation should be discouraged with lower extremity EZ-IO Catheters in place. For the proximal humerus IO site, movement in the affected arm should be minimized (ideally abducted no more than 45 degrees) but never past 90 degrees (e.g. elevated above shoulder level), as this may lead to needle dislodgement. There are no activity restrictions after EZ-IO Catheter removal unless instructed by the treating clinician.

Removal

To withdraw the catheter, remove the EZ-Connect Extension Set and EZ-Stabilizer dressing. Attach a Luer Lock syringe to the hub. While maintaining axial alignment, twist the syringe and catheter clockwise while pulling straight out. **Do not rock or bend the catheter during removal.** Dispose of all sharps in a proper sharps container. Apply pressure over the site as needed. Dress the site.

Post-IO removal, monitor and/or instruct the patient and family or health care provider to monitor the involved limb for any signs of delayed presentation of symptoms of potential complications including, but not limited to, fever, discoloration, swelling, pain (with active or passive motion), paraesthesias, skin feeling cool or warm, pulses, firmness, or taut feel to area as compared to other limb.

References:

- 1 Davlantes C, Puga T, Montez D, Philbeck T, Miller L, DeNoia E. 48 Hours dwell time for intraosseous access: A longer-term infusion using a temporary solution. *Crit Care Med* 2016;44(12):140.^{TS}
- 2 Fowler RL, Pierce A, Nazeer S, et al. 1,199 case series: Powered intraosseous insertion provides safe and effective vascular access for emergency patients. *Ann Emerg Med* 2008;52(4):S152.^{TS}
- 3 Philbeck TE, Miller LJ, Montez D, Puga T. Hurts so good; easing IO pain and pressure. *JEMS* 2010;35(9):58-69.^{TS}
- 4 Overbaugh R, Davlantes C, Miller L, Montez D, Puga T, Philbeck TE. Intraosseous vascular access catheter appears safe during extended dwell: A preliminary report. *Ann Emerg Med* 2015;66(4):S5.^{TS}
- 5 Montez D, Puga T, Davlantes C, Philbeck T. IO infusion pain mitigation in the sternum and proximal humerus: Establishing a regimen. *Crit Care Med* 2016; 44(12):154.^{TS}
- 6 Atanda A Jr, Statter MB. Compartment syndrome of the leg after intraosseous infusion: guidelines for prevention, early detection, and treatment. *Am J Orthop* 2008;37:E198-200.
- 7 Tsung HW, Blaivas M, Stone MB. Feasibility of point-of-care colour Doppler ultrasound confirmation of intraosseous needle placement during resuscitation. *Resuscitation* 2009;80:665-8.
- 8 Saul T, Siadecki SD, Berkowitz R, Rose G, Matilsky D. The accuracy of sonographic confirmation of intraosseous line placement vs physical examination and syringe aspiration. *Am J Emerg Med* 2015; article in press. <http://dx.doi.org/10.1016/j.ajem.2014.12.034>.

EZ-IO Driver and Training Driver

The EZ-IO Driver is a sealed, hand-held, lithium battery-powered medical device.

Useful Life of EZ-IO Driver

The useful life of the driver is stated in the IFU as up to 500 insertions with the disclaimer already listed and the shelf life is 10 years. However the life expectancy and number of approximate insertions is dependent on multiple factors: actual usage, bone density, insertion time, storage conditions, and frequency of driver testing. As with any emergency medical device, carrying a backup is strongly advised.

- EZ-IO Driver LED will be solid green when trigger is activated and has sufficient power
- EZ-IO Driver LED will blink red when the trigger is activated, and the driver is approaching the end of its battery life, indicating that the EZ-IO Driver must be replaced

Do not use excessive force during insertion. Let the EZ-IO Driver do the work, and allow the beveled needle set to cut through the bony cortex as it is slowly advanced. Applying too much pressure on the driver (especially during insertions in the tibia, where the cortex is thicker) may cause the user to perceive that the driver is “bogging down” or losing power during insertion.

Battery Information:

- EZ-IO Drivers are sealed and not intended to be opened
- Batteries are not replaceable

Storage:

- The EZ-IO Driver and accessories may be stored at temperatures between -20°C to 50°C (-4°F to 122°F)
- When storing in the yellow, soft-sided case (Vascular Access Pak, VAP) remove the trigger guard to prevent accidental activation of the EZ-IO Driver
- Additional product information can be found in the driver Instructions for Use and at www.ArrowEZIO.com

In the unlikely event of driver failure, remove the EZ-IO Driver, grasp the needle set by hand, and advance the needle set into the medullary space while twisting the needle set clockwise/anticlockwise as described below in the Manual Insertion Technique.

Manual Insertion Technique*

1. Push needle set tip through the skin until tip rests against the bone (if not already partially penetrated with the driver). At least one black depth mark must be visible above the skin for confirmation of adequate needle set length.
2. Hold the needle set with the catheter hub and stylet as one piece (ensuring the stylet and hub remain screwed together).
3. Rotate clockwise/anticlockwise while applying gentle, moderate, steady downward pressure without rocking the needle set. Allow rotation and pressure to penetrate the bone cortex, not excessive force.
4. Stop insertion when a change in resistance is felt as a “give” or “pop” indicating entry to medullary space in paediatric patients. In adult patients, advance needle set approximately 1-2 cm after entry into medullary space (felt as a change in resistance); in the proximal humerus for most adults, the needle set should be advanced 2 cm or until hub is flush or against the skin.
5. Stabilise needle set hub and remove stylet.
6. Proceed as usual.

* Manual insertion of IO access is recommended only when the driver is unavailable or inoperable. Use of the driver optimises tactile feedback and sensitivity. Clinicians can more easily discern when the needle set passes from the hard outer bone cortex into the less dense medullary space.¹ The mechanised driver creates a clean entry hole the size of the catheter.² See Figures 28a and 28b.

References:

- 1 Miller L, Philbeck T, Bolleter S, Garcia G. Tactile feedback comparison of three types of intraosseous access devices for needle insertion accuracy. *Ann Emerg Med* 2010;56(3):S133.^{TS}
- 2 Teleflex internal study done in cadaveric bone.

EZ-IO Driver Cleaning

Specific information and direction on the EZ-IO Driver cleaning is outlined below. This information can also be found in the EZ-IO Driver's Instructions for Use. The instructions can also be found at www.ArrowEZIO.com.

Cleaning and Disinfection of the EZ-IO Driver:

1. Maintain BSI or PPE precautions.
2. Wipe entire exterior surface of EZ-IO Power Driver with soft, clean moistened cloth. Use soft bristled brush to remove any visible soil.
3. Spray exterior surface with anti-microbial solution following the solution manufacturer's specific recommendations.
4. Gently wipe exterior surfaces with gauze pads until visible debris is removed.
5. Clean and manipulate trigger using cloth moistened with anti-microbial solution.
6. Using sterile swabs, moisten with anti-microbial solution, gently clean inside opening around metal drive shaft.
7. After cleaning, inspect to ensure no visible debris remains, and no damage has occurred.
8. Dry driver with a soft, clean cloth and return to appropriate location.

Do not immerse or use excessive amount of liquid when performing cleaning and disinfecting.

EZ-IO Training Driver

The EZ-IO Training Driver is intended for training and demonstration only. Training drivers typically incur heavier usage, more frequent transport, and frequent handling by inexperienced users. Regulatory, quality, and cleaning differences preclude the training driver from being used for patient care.

Trigger Guard/Vascular Access Pack (VAP)

The Arrow EZ-IO Vascular Access Pack is a soft sided yellow case that includes a built-in cradle for the driver. Storing the driver in the cradle with the trigger guard in place may cause inadvertent activation of the driver, resulting in depletion of the batteries. To prevent this situation, the trigger guard should be completely removed when storing the driver in the cradle.

EZ-Connect Extension Set

The EZ-Connect Extension Set (extension tubing with a 90° angle, supplied with needle set) is a needleless connector system with a split septum (non-mechanical) valve, swabable negative fluid displacement port and Luer Lock adapter. The needleless connector enables attachment of a syringe to the extension set, rather than directly attaching a syringe to the EZ-IO Catheter (which should be avoided unless aspirating for laboratory samples, administration of very small volume medication doses and other special circumstances). The EZ-Connect Extension Set is low-profile, designed to prevent kinking of the extension tubing, secures the EZ-IO Catheter in place with the EZ-Stabiliser dressing, and helps prevent accidental dislodgement.

The EZ-Connect Extension Set contains approximately 1 ml of volume when primed. The EZ-Connect Extension Set was bench tested in 2010 to determine the power infusion pressure at which the EZ-Connect tubing ruptures. This test was conducted three times, each with a new EZ-Connect Extension Set and the EZ-Connect Extension Set clamped. The EZ-Connect Extension Set ruptured at 200 psi, 195 psi, and 190 psi.¹

Infection Prevention/Control

The EZ-Connect Extension Set uses the Robertsite Needleless Connector by Halkey Roberts. Studies evaluating the integrity of the valve's microbial properties found the system maintains adequate microbial barrier protection.²

Observe the following instructions for proper use of the EZ-Connect Extension Set:

- Do **NOT** use any instruments to tighten connections
- 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
- Prior to accessing the valve, swab the surface of the valve with alcohol and let it air dry (or follow your institution's policy/protocol)

All components of the EZ-IO System, including the EZ-Connect Extension Set are DEHP-free and are not manufactured using natural rubber latex.

EU: The EZ-Connect Extension Set is compatible with any syringe or connector made to the ISO/IEC DIS 80369-7 specification.

References:

- 1 Vidacare Study #2010-16, internal bench test data, Teleflex Incorporated. Test data may not be indicative of clinical performance.
- 2 <http://www.halkeyroberts.com/userfiles/files/Medical%20Miscellaneous/RNV%20Book/RNV%20Book%202016.pdf> Accessed: 02/08/2017.

Complications

What Are the Complications Associated with IO Vascular Access?

Historically, the overall rate of serious complications associated with IO insertion and infusion has been less than 1%. [See Intraosseous Complications, page 38]

- Extravasation or infiltration of fluid is the most commonly reported complication of IO catheters
- Compartment syndrome can result if a large extravasation or infiltration goes undetected, which may require surgical intervention or amputation
- Osteomyelitis is a rare but serious infection. The most often-quoted rate is 0.6% from a published 1985 meta-analysis by Rosetti of IO procedures done before the availability of modern techniques and devices.³ In the absence of a more recent study, the literature and Teleflex records indicate a much lower rate – fewer than one incident per 100,000 insertions. [See Osteomyelitis, page 46]

Rare complications also include localised infections, penetration through posterior cortex of the bone, catheter breaking, bending or clogging, dermal abrasion, and difficulty removing the IO device. Complications can usually be prevented or limited by proper insertion technique and frequent monitoring of the infusion site.⁴ For further information visit: <http://www.teleflex.com/ezioeducation/index.html> [See Intraosseous Complications, page 38]

Will Infusing Drugs Through the IO Space Cause Long-Term Damage to Bone Marrow?

No long-term damage to human bone has been documented in known medical literature from routine intraosseous infusions; however, caution is advised with the use of long-term or repeated infusions of hypertonic agents in the same bone. A 1947 review of 495 paediatric patients with IO placement found that two patients who received IO hypertonic saline infusions developed osteomyelitis and advised against infusing hypertonic fluids via the IO route.⁵ A 1997 review of preclinical and clinical studies reported that hypertonic saline could be infused through the IO route in combat situations, but recommended limiting the infusion to a single dose.⁶ Most published studies are preclinical and suggest short term doses of hypertonic solutions and vesicants to be safe in the preclinical setting.⁷ One preclinical study in swine reported Adriamycin, administered in the same bone three times over a 72-day period, caused osteomyelitis and/or fractures in the bones used for the infusions in 10 of 14 animals. The authors did a follow-up study designed to explore different drug administration regimens designed to prevent these complications. The IO delivery of lower dose and diluted concentrations of Adriamycin was determined to be safer and resulted in less tissue abnormality when compared with higher dose/higher concentration. Authors concluded that use of the IO route with rotation of sites may be a feasible option for Adriamycin or other vesicant delivery.⁸ A 2002 preclinical study in swine reported marrow damage after multiple infusions of hypertonic saline.⁹ Any drug with the potential to cause sclerosis or damage to veins has the potential to damage intraosseous vessels and tissue especially with repeated or long-term doses. As such, the risk versus benefit ratio of administering these drugs via the IO route should be carefully evaluated prior to use. Potential mitigation practices would include rotation of sites, flushing of the medullary space post-infusion with normal saline, and use of diluted concentrations when acceptable. [See Effects of IO Access on Growth Plates and Bone Repair, page 42]

Does IO Insertion or Infusion Affect the Growth Plate in Paediatric Patients?

Though often listed as a theoretical complication of IO access, no growth plate damage in paediatric patients has been documented in known medical literature. [See Effects of IO Access on Growth Plates and Bone Repair, page 42]

Is Fat Embolism or Thromboembolism an Issue With IO Infusion?

Clinically significant fat embolism from IO administration has not been reported in known medical literature. [See Embolism, page 43]

Is Air Embolism a Possibility through an IO Catheter?

Yes. Air embolism can be introduced into the circulatory system by any vascular route including peripheral venous access, central venous access, arterial access, or intraosseous access. A primed syringe, extension set or infusion tubing should always be placed on the IO catheter hub immediately after EZ-IO Catheter insertion.

Does Teleflex Track Complications Associated with the EZ-IO Device?

Yes. Teleflex tracks any reported problems or complications associated with the EZ-IO Device in accordance with U.S. FDA and global out of the United States (OUS) country-specific regulatory agency requirements for medical devices.

References:

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Intraosseous Complications

Historically, the documented overall complication rate associated with IO insertion and infusion is less than 1%.^{1,2} In a 1985 meta-analysis of over 4,200 patients, the most common IO complication was infection, including osteomyelitis (0.6%), and was attributed to IO placement in bacteremic patients or prolonged infusions.³

With modern technological devices and procedures, extravasation is the more prevalent complication reported.^{4,5} While simple extravasation itself may be unremarkable, compartment syndrome may occur if extravasation continues undetected and may be the most common severe complication of IO access.^{2,6} As with IV access, extravasation of certain medications may cause damage to soft tissue. Therefore, careful monitoring of the insertion site is imperative. [See Compartment Syndrome, page 40]

Although uncommon, other reported complications have included fracture, soft tissue and/or dermal damage, failure to infuse due to catheter bending or clogging, and emboli potentially related to IO access.^{7-11,21,22}

EZ-IO Device Complications

As of May 2017, over 85 clinical trials or case studies involving the EZ-IO Device have been reported in the clinical literature, including over 5,400 patients.¹² The rate of EZ-IO Device related serious complications reported in literature and to Teleflex through clinical communications and global regulatory channels is <0.001% (less than one per 100,000 EZ-IO Catheter placements based on three million needle sets sold). The most frequently reported serious complication is compartment syndrome which has been reported with three resulting in amputations.¹³⁻²⁰ Two cases of osteomyelitis have been reported through clinical communication and filed with the FDA's Medical Device Reporting (MDR) system, but none have been reported for the EZ-IO Device in the literature.

Non-serious complications included uncomplicated extravasation, infiltration, slow flow rate, dislodgement, inability to flush, leakage, problems with device, difficulty with removal of device, local inflammation, and a case of dermal abrasion.²¹ Complications can usually be prevented or severity minimised by proper insertion technique and frequent monitoring of the infusion site.

In a 2005 prospective study of the EZ-IO Device in 250 adult patients, Davidoff et al. reported an overall complication rate of 3%, with failure to deliver medications the most predominant.²³ These complications were generally associated with failure to syringe-flush the catheter following insertion – a critical step for IO infusions. There were no cases of osteomyelitis, embolism, fracture, infection, extravasation, or compartment syndrome.

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Compartment Syndrome

Compartment Syndrome Overview

“Compartments” are composed of muscle tissue, nerves, and blood vessels separated and surrounded by thick layers of non-expandable tissue (fascia). Compartment syndrome occurs when swelling within that confined space causes the compression of those nerves, blood vessels, and muscle due to the lack of ability to expand outward. This may be caused by instillation of fluid into the soft tissue outside the vascular space. The most common site for compartment syndrome is the lower leg. The swelling within the compartment can progress to compression of blood vessels within the compartment causing a lack of oxygenation and eventually, necrotic tissue. When the condition is attributed to IO access, compartment syndrome is usually secondary to infiltration and/or extravasation – the most prevalent complication of all forms of IO vascular access, including the EZ-IO Device.¹ Compartment syndrome usually occurs when clinicians do not recognise early signs of infiltration and/or extravasation, and may be secondary to inadequate needle length leading to incomplete penetration of the cortex, overpenetration through the opposite cortex, extravasation through the foramina of a nutrient vessel, multiple punctures (for example, due to multiple IO access attempts) in the same bone, fracture, and needle dislodgement. In his discussion of compartment syndrome, Paxton notes that the potential risk may also be influenced by factors which include the type of fluid (e.g., fluid osmolarity, isotonic vs. hypertonic), length of infusion, total volume, and rate of fluid infused.^{2,3} In extreme cases, amputation of a limb is necessary if the compartment syndrome is not recognised soon enough or is not adequately treated. Once recognised, treatment of compartment syndrome consists primarily of removing the increased pressure source and careful monitoring, assuming circulation has not been compromised. In more severe cases, fasciotomy (surgically opening the fascia surrounding the compartment to release the pressure) may be required to restore circulation.

IO Access-Associated Compartment Syndrome in the Literature

Eight paediatric cases of compartment syndrome were reported in the medical literature between 2008 and 2016.^{2,4-9} Contributing factors included improper technique, catheter dislodgement, and prolonged infusion with caustic agents. Published adult cases include a 2011 case in which IO access was achieved on the second attempt in the same limb (clinicians did not believe the first attempt penetrated the cortex) and ten hours post-infusion, symptoms of ischemia were present. The authors removed the IO catheter and a compartment release was done.¹⁰ A second case of adult compartment syndrome related to IO infusion was reported in 2013 in which IO access was established in the fractured tibia of an adult multi-trauma patient for fluid infusion.¹¹ IO catheter placement is contraindicated for fractured bones. Other cases of compartment syndrome have occurred using manual IO devices; two resulting in limb amputations. The first known case of humeral compartment syndrome presumed to be due to IO access in the affected limb was reported in a 2017 case study. In this case a patient with a severe coagulopathy developed compartment syndrome eight days post-IO catheter removal requiring treatment with a fasciotomy.¹²⁻²¹

These cases underscore the importance of adequate training, appropriate selection of IO needle set and insertion site, proper technique, confirming proper placement of the IO catheter within the medullary space, frequent reassessments, and stabilisation of all IO devices. Early detection of extravasation and prevention of compartment syndrome can usually be accomplished through frequent monitoring of the insertion site and the involved extremity, particularly during prolonged infusion, prolonged transport times, in patients with multiple co-morbidities such as coagulopathic conditions, and during administration of large fluid volumes, vasopressors, and vesicants.^{2,22}

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Effects of IO Access on Growth Plates and Bone Repair

Effect on Epiphyseal (Growth) Plates

A 1990 review article published in the *New England Journal of Medicine* stressed the relative safety of IO vascular access and reported earlier findings of a lack of evidence for lasting negative effects of IO infusion on the bone, growth plates, and marrow elements.¹ Lack of negative effect on the epiphyseal plate subsequent to IO infusion has been demonstrated in several radiographic studies in the paediatric population. Preclinical studies in swine and rabbit models have supported similar conclusions.²⁻⁴

Clinical Research

A 1947 clinical study examined long-term bone abnormalities during radiographic follow-up in 72 paediatric patients who received IO insertion. No patient exhibited radiographic bone abnormality and bone growth was normal for all patients in the study. Thirty-six of those patients were followed up to a year; 18 were followed up to two years and 18 were followed over two years post-infusion.⁵ A 1997 study performed radiographic measurements of the tibias in paediatric patients 12 months after IO infusion. Results demonstrated no significant difference in tibial lengths.⁶ In 2003, a clinical study of paediatric patients receiving IO infusions revealed no radiographic differences in tibia width or length. The follow-up radiographs were performed on average 29 months after infusion.⁷ A 2003 overview article is also supportive of these findings.⁸

Preclinical Research

One preclinical study of IO infusion in young swine found no growth disturbances or growth plate abnormalities after two and six months.² Another preclinical study found IO infusion of saline and bicarbonate did not damage growth plates. The researchers observed loss of bone trabeculae supporting the growth plate, but the loss was rapidly repaired.³ A 1993 preclinical study found no changes in bone growth or epiphyseal injury related to IO infusion.⁴ Boysen's 2016 swine study compared administration of tranexamic acid (TXA) by the IO and IV route. To assess for potential bone marrow lesions caused by drug toxicity, a pathologist did blinded postmortem histological microscopic assessments of sections of the proximal tibial articular cartilage, epiphysis, growth plate, and metaphysis in limbs that had the IO TXA infusion with the non-affected limb. All marrow was normal with no differences between limbs.⁹

Bone Repair after IO Infusion

The Rosetti meta-analysis (1985) reported multiple follow-up studies on marrow and bone from 24-hours post infusion through 22 months.¹⁰ Periostitis at the injection site cleared within 2-3 weeks; marrow cellularity after isotonic infusion was slightly less or normal; and no long-term bone changes were noted post isotonic infusion.

Based on a 2010 preclinical study, sealing of the bone (to the point at which IO placement and infusion can be accomplished in the same bone) takes approximately 48 hours post-IO catheter removal.¹¹ Early IO research articles suggested an interval of 48 hours before attempting an IO infusion in a limb previously accessed.¹² By that time, fibrin formation and clotting may be sufficient to prevent extravasation through the previous IO hole¹⁰ since bone marrow fluid rapidly undergoes coagulation and fibrin formation.¹³ Complete healing, to the point where x-ray can no longer detect the hole, varies from weeks to months.¹⁴

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Embolism

Thromboembolism

Thromboembolism is not typically a complication associated with IO infusions due to anatomy and physiology of circulation within the medullary cavity. One known case is reported in the literature for an arterial thrombosis in a patient receiving an IO infusion. The authors were not certain of the cause of the thrombosis and exact mechanisms of the disease process were unclear.¹ Two additional known cases have been reported through the FDA MedWatch system on infants that had multiple cardiac co-morbidities and after prolonged cardiac arrest before return of spontaneous circulation.²

Air Embolism

As with any vascular access route, an air embolism can be introduced into the circulatory system by IO access. The determining factors favoring air embolism are relative pressure gradients between the vascular access site and atmospheric pressure, and the size of the catheter.

There are two known reports in published literature of air embolism in paediatric patients after an IO infusion. In the first case, a cerebral arterial air embolism was noted on autopsy in a seven month-old child.³ While the cause of death remained undetermined, it was noted that the patient had no other vascular access other than the IO route. However, the authors noted that air could have been introduced during any of the attempts at central venous or arterial access, as well as by the IO route.

In the second case, multiple gas emboli were discovered in a post-mortem computed tomography (CT) scan in a four month-old child who died of sudden infant death syndrome.⁴ A bone marrow aspiration needle had been used to provide IO vascular access. No alternative attempts at vascular access were noted. The author concluded that gas could have been introduced subsequent to the method of infusing IO medications, and concluded that resuscitation with an inserted, disconnected intraosseous needle/catheter should be avoided.

A 2016 case reported on a patient in which they found a vascular air embolism via ultrasound when they were assessing the patient's femoral vessels prior to arterial line placement on the same side as a limb that had an IO access placed. The authors noted that it was possible air was introduced when the patient injected IV heroin to that same leg; but believe it was more likely the IO line or tubing was not flushed or left open for a period of time.⁵

One report of an air embolism potentially related to IO infusion is within the FDA MDR database. The embolus was diagnosed by CT scan. The air embolus was removed by syringe aspiration from the vessel without subsequent complications.

A primed syringe, extension set or infusion tubing should always be placed on the IO catheter hub immediately after insertion, and should remain in place until catheter removal to help prevent the possibility of air embolism.

Fat Embolism

No known case of clinically significant fat embolism resulting from IO administration has been reported in the medical literature, although preclinical trials have shown microscopic fat emboli in the lungs after high pressure IO infusion.⁶⁻⁸

The risk of fat embolism associated with IO infusion has been studied in preclinical trials and reported in the clinical literature. In a canine study, Orłowski et al. examined the prevalence of fat and bone marrow emboli in the lung following IO infusion of hypertonic and emergency drugs.⁹ Researchers found no difference in the mean number of fat and bone marrow emboli per square millimeter of lung tissue compared to the control group, who received normal saline by the IO route. In 1995, Plewa reported a preclinical study examining hematologic parameters with IO and IV autologous blood transfusions.¹⁰ The authors found all haematologic parameters remained within normal limits in both IO and IV groups, and concluded that IO blood transfusions were haematologically safe, without risk of appreciable haemolysis, disseminated intravascular coagulation, or fat embolism syndrome.

A 1997 swine study examined IO infusion during CPR and found no increase in fat embolism in the IO group compared to control groups, which received no IO infusions.⁷ Another swine study found low levels of fat embolism (one to three emboli per high powered field in 30% of the specimens). The researchers concluded that the risk of fat emboli exists with IO access, but its clinical relevance is unclear.¹¹ The high pressure value reported in the study does not align with the number reported here. Were the infusion rates reported averaged together? If so, that's 606 mmHg. Could reword to indicate the pressures individually to be accurate and avoid recalculating the study's numbers.¹² The infusion pressures were double the maximum pressure typically used for IO infusion and, in contrast to Orłowski's earlier work.

Rubal's 2015 swine study investigated the occurrence of fat intravasation resulting from IO flush and infusion. Intravasated fat was assessed using a lipophilic fluoroprobe and vascular ultrasound imaging. Fat intravasation was observed during all IO infusion regimens, with subclinical pulmonary fat emboli persisting 24 hours post infusion. It was noted that initial flush was a significant factor in fat intravasation, low levels of intravasation occurred with infusions ≤ 300 mmHg, fat intravasation and bone marrow shear-strain increased with IO infusion rates, and intravasation was influenced by insertion site.⁸

In a case series of 18 paediatric patients receiving IO infusion during resuscitation, one complication of minor fat embolism was reported and described by Moller as having "no clinical significance."¹³

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Osteomyelitis

Numerous research studies and reports in clinical literature have addressed the low incidence of osteomyelitis risk in the IO space.

In a 1985 meta-analysis of IO complications in over 4,200 patients, the most common IO complication was osteomyelitis at 0.6% and was attributed to IO access placement in bacteremic patients or prolonged infusions.¹ Six osteomyelitis cases have been reported in known literature since the 1985 meta-analysis by Rosetti et al.²⁻⁷

As of May 2017, over 85 clinical trials or case studies involving the EZ-IO Device have been reported in the clinical literature, involving over 5,400 patients. In aggregate, study results have reported no cases of osteomyelitis. While not reported in a published study, two cases of osteomyelitis subsequent to EZ-IO Device use have been reported to the manufacturer through clinical communications. One case involved a paediatric patient with multiple co-morbidities, including sepsis. Upon initial follow up the patient was steadily improving, but complete follow up data was unavailable. The second case was an elderly patient treated with IV antibiotics.⁸

Medications/Fluids

What Fluids and Medications Can Be Infused Via the IO Route?

Many fluids or medications that can be safely infused via peripheral IV route may be infused through the IO route using the same dose, rate, and concentration.¹⁻⁴ Incompatible drugs and fluids should be infused sequentially in a manner consistent with standard IV infusion practice. Caution should be exercised with repeat doses of hypertonic fluids. Routine infusions of chemotherapy agents is not recommended; but if chemotherapy must be given via IO access extreme caution is advised, and follow each infusion with a normal saline infusion to flush the chemotherapeutic agent out of the marrow space.

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What Dosages Are Required for IO Infusion Compared with IV Dosages?

Intraosseous dosages are typically identical to IV dosages. Clinical and preclinical studies demonstrate most drugs and fluids reach the central circulation with similar concentrations and clinical effects through the IO route and the IV route.³⁻²³

What Medications Have Been Administered Successfully to Date (Via the IO Route)?

A list of medications that have been included in the clinical literature as administered via the IO route follows on page 48.

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The infusates listed below were delivered via the IO route and referenced in clinical literature:

- Adenosine^{1-6,62}
- Albumin^{7,8}
- Alfentanil⁹
- Alteplase^{10,11,12}
- Aminophylline¹³
- Amiodarone^{13,14,15,16}
- Ampicillin^{14,17}
- Anaesthetic agents^{18,19,20}
- Antibiotics^{17,21,22,23,59}
- Antitoxins²⁴
- Anti-meningococcal antitoxin²⁵
- Anti-pneumococcus serum²⁵
- Anti-tetanus serum²⁶
- Atracurium besylate^{9,27}
- Atropine^{13,14,28,29}
- Aztreonam¹⁴
- Benzylpenicillin (Penicillin G)⁵⁹
- Blood and blood products^{7,13,14,18,26,29-33,59}
- Bretylium³⁴
- Calcium chloride^{14,32}
- Calcium gluconate³⁵
- Cefazolin²¹
- Cefotaxime²²
- Ceftriaxone¹⁴
- Centruroids (Scorpion) Immune F(ab)2 (Equine) Injection (Scorpion Antivenom-trade: Anascorp)^{24,36}
- Cisatracurium besylate³⁷
- Contrast media^{29,38-42}
- Dexamethasone^{29,32}
- Dextran²⁹
- D5W⁹
- D5 ½NS¹⁴
- Dextrose 10%¹⁴
- Dextrose 25%¹⁴
- Dextrose 50%^{13,14}
- Diazepam^{34,43}
- Diazoxide²⁹
- Digoxin⁵¹
- Diltiazem¹⁴
- Diphenhydramine¹⁴
- Dobutamine hydrochloride^{14,21}
- Dopamine^{13,14,45}
- Ephedrine⁹
- Epinephrine^{13,14,31,59}
- Etomidate^{13,14,46}
- Fentanyl^{13,14,47}
- Flucloxacillin (floxacillin)⁵⁹
- Fluconazole¹⁴
- Flumazenil⁴⁶
- Fosphenytoin¹⁴
- Furosemide¹³
- Gentamicin^{7 14}
- Haloperidol³⁷
- Hartmann's Solution (Compound Sodium Lactate Solution)^{29,48,59}
- Heparin^{14,15,29}
- Hydroxocobalamin^{46,49}
- Hydrocortisone¹⁹
- Hydromorphone¹⁴
- Hypertonic saline/dextran (7.5% NaCl/6% dextran)⁵⁰
- Insulin^{14,51}
- Isoprenaline⁹
- Ketamine^{14,19,47,52,59}
- Labetalol³⁷
- Lactated Ringer's Solution^{9,13,29}
- Levetiracetam¹⁴
- Lidocaine^{13,14,29,30,56-58,60}
- Linezolid¹⁴
- Lorazepam^{14,37}
- Magnesium sulfate^{14,37}
- Mannitol³²
- Methylprednisolone sodium succinate^{14,37}
- Midazolam^{13,14,21,59}
- Mivacurium⁹
- Morphine sulfate^{14,32,47,53,59}
- Nalbuphine⁹
- Naloxone^{13,14}
- Neostigmine^{9,19}
- Norepinephrine^{13,14}
- Normal saline¹³
- Ondansetron¹⁴
- Pancuronium^{20,21}
- Paracetamol⁹
- Penicillin²¹
- Phenobarbital¹⁴
- Phenylephrine¹⁴
- Phenytoin^{14,32,54}
- Piperacillin¹⁴
- Potassium chloride³⁷
- Promethazine^{13,14}
- Propofol^{30,59}
- Recombinant fVIIa⁵⁹
- Remifentanil⁹
- Rocuronium^{13,14,30,52}
- Sodium bicarbonate^{13,43}
- Standard IV solutions¹³
- Succinylated gelatin solution 4% (Gelofusine)⁵⁵
- Succinylcholine (suxamethonium)^{9,13,27,43,52,59}
- Sufentanyl⁴⁶
- Tenecteplase^{15,28}
- Thiamine^{13,14}
- Thiopental^{27,32}
- Tobramycin sulfate¹⁴
- Tranexamic acid^{18,61}
- Vancomycin^{14,17}
- Vasopressin^{13,14}
- Vecuronium^{14,28,32,59}
- Vitamin K⁷

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Pain Management for IO Infusion

While the discomfort associated with IO insertion is variable, pain associated with IO infusion under pressure can be more severe.¹ Consider slow administration of two percent (2%)* preservative-free and epinephrine-free lidocaine given via syringe into the IO catheter as a local (within the medullary space)** anaesthetic for patients responsive to pain. Two percent (2%)* preservative-free and epinephrine-free lidocaine (sometimes referred to as “cardiac lidocaine”) has been shown to be effective in limiting or alleviating IO infusion pain. Lidocaine administered via the IO route for anaesthetic effect should be delivered slowly into the catheter so as to remain in the IO space long enough to achieve a local anaesthetic effect prior to administering the saline flush.

A 2016 abstract noted that the use of additional analgesics may be an effective alternative to lidocaine alone and mitigate the need for repeat lidocaine dosing.²

* 2% preservative-free and epinephrine-free lidocaine may not be available globally; refer to total dose in milligrams.

** Locally administered into the catheter for anaesthesia within the medullary space for IO infusion pain.

Conscious Patients/Lidocaine Dosing

Review manufacturer’s lidocaine instructions for use prior to administration and observe recommended cautions/contraindications to using 2% preservative-free and epinephrine-free lidocaine. Teleflex does not manufacture lidocaine. A number of articles in the literature describe clinical experience with lidocaine administration for IO infusion in patients responsive to pain.¹⁻¹² These cited sources document initial lidocaine doses ranging from 20-80 mg, with varying doses for maintenance. For additional information visit: <http://www.eziocomfort.com>

A 2010 article reported the combined results of two studies examining pain management with IO vascular access.¹ These volunteer studies using the humerus and tibia demonstrated that less pressure was required to infuse through the humerus than the tibia route, and demonstrated a direct correlation between infusion pressure and pain level (i.e. increased pain with greater infusion pressures).

During the 90-minute observation period in the tibial study, eight of ten volunteers who had previously received 100 mg lidocaine required an additional 20 mg lidocaine to keep the IO infusion pain level below five (on a scale of 0-10). No volunteers in the humeral study, who had previously received 60 mg lidocaine, required additional lidocaine dosing to keep pain levels below five. This article demonstrates the proximal humerus may be a preferred IO site for conscious patients.

A volunteer study done in 2016 compared 2% preservative-free and epinephrine-free lidocaine doses of 40 mg followed by a flush, followed by placebo or an additional 20 mg dose, in the sternum and proximal humerus sites. Conclusion of this study states: "Infusion pain through a PH IO may be managed with a single 40 mg lidocaine prior to infusion, but a total of 60 mg may be considered for sternal IO infusion." Results state that the mean pain score was statistically different between a 40 mg dose vs a 60 mg dose but that this was not shown clinically.

Lidocaine and appropriate dosages must be prescribed by a qualified prescriber.

IO Infusion Pain Management Using 2% Lidocaine (preservative-free and epinephrine-free)

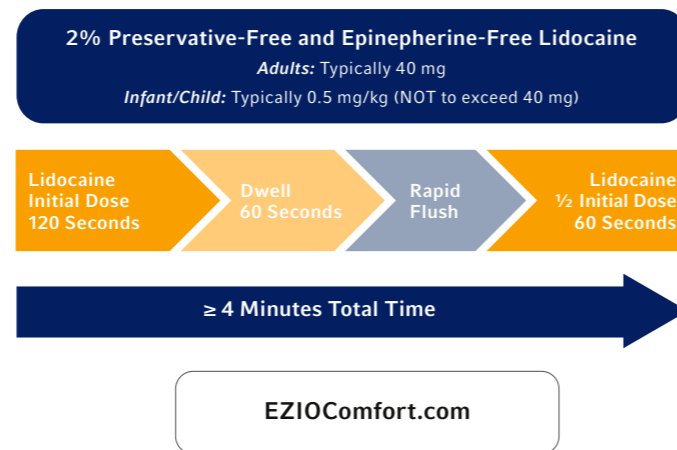
Review lidocaine manufacturer's IFU prior to administration and observe recommended cautions/contraindications.

With the stabilizer in place, carefully attach syringe directly to IO catheter 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)
2. Flush IO catheter with normal saline
 - Adult flush: 5-10 mL
 - Infant/Child flush: 2-5 mL
3. Slowly infuse lidocaine (half of initial dose) over 60 seconds
4. Attach extension set primed with normal saline and flush

Repeat PRN. Consider systemic pain control for patients not responding to IO lidocaine.

Figure 26



Consider systemic pain control for patients not responding to IO lidocaine

Disclaimer

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. The information provided here 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 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 disclaims all liability for the application or interpretation of this information in the medical treatment of any patient.

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Paediatrics: Newborns, Infants, Children, and Adolescents

The U.S. Food and Drug Administration (FDA) defines the paediatric population as being from newborn to 21 years of age using four paediatric subgroups. The FDA recognises that the descriptions are somewhat arbitrary and that weight, body size, physiological development, neurological development, and neuromuscular coordination may often be more appropriate indicators than chronological age.

- Birth to 1 month of age. Newborn
- > 1 month to 2 years of age. . . . Infant
- > 2 to 12 years of age. Child
- > 12 to 21 years of age. Adolescent

For the purpose of describing paediatric patients in relationship to IO vascular access, the above subgroups will be used. For IO vascular access devices, adolescents are usually considered adults. <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089742.pdf> (Accessed 7/25/2017)

EZ-IO Device: Indications in Paediatric Patients

The EZ-IO Device is indicated for patients weighing 3 kg or over. The EZ-IO System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and paediatric patients, and the distal femur in paediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours in non-CE indicated markets and 72 hours in CE indicated markets. For patients > 12 years old use of the device may be extended for up to 48 hours when alternate intravenous access is not available or reliably established.

Can a 25 mm or 45 mm Needle Set Be Used in a Paediatric Patient?

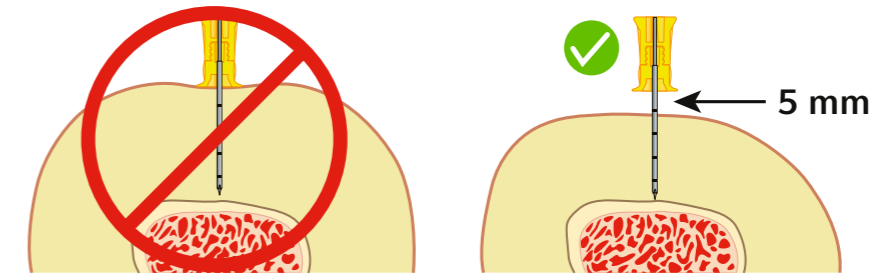
The EZ-IO Needle Sets do not have “adult” or “paediatric” designations. Each needle set is indicated with guideline weight designations.* The 25 mm needle set is indicated for 3 kg or over. The 45 mm needle set may be considered when the patient’s weight is 40 kg or over or there is excessive tissue overlying the insertion site and for most adult humeral insertions. Clinical judgment should be used to determine appropriate needle set selection based on patient anatomy, insertion site, weight, and tissue depth. Just as a small adult

patient may require a shorter length catheter, an obese child may require a longer catheter. The EZ-IO Catheter is marked with a black line approximately 5 mm from the hub. Black lines on each catheter function as depth measuring guides to help identify if the needle will be long enough to seat properly in the medullary space by identifying soft tissue depth (see figure 27 on following page). If the EZ-IO Needle Set is inserted through the soft tissue and does not reach the bone or a black mark is not visible above the skin, a longer needle set or alternate site should be chosen prior to penetration of the cortex.

The ability to control insertion depth of the needle set tip into the target bone is necessary for safe and effective intraosseous access. The depth of penetration is determined by sensing when the needle set has penetrated through the dense cortex and has entered the softer medullary cavity with cancellous bone. This endpoint is recognised by the “pop” or “give” that is felt when the needle reaches the target area. With the exception of adult proximal humerus insertions, routinely inserting the needle set to the hub is not recommended technique, especially in paediatric patients. If the needle is inadvertently advanced past the target area, it is possible to “feel” the needle tip hitting the distal cortex which allows the operator sufficient time to stop insertion before the opposite cortex is breached. The risks associated with an insertion that is either too shallow or too deep (through the opposite cortex) are similar. Proper technique that uses the black lines, tactile feedback technique, the placement confirmation steps listed in the Instructions For Use (IFU), and diligent reassessment mitigate those risks.

* Soft tissue depth over insertion sites can vary depending on individual anatomical characteristics. Therefore, the needle length required to reach the intraosseous space can vary from one patient to the next even if they fall within the same age group and/or weight and height range. Needle set selection starts with the general weight ranges but ultimately, the true measurement can be found by use of the black line, and post-insertion placement confirmation steps to further validate correct insertion depth. [See Selection of Appropriate Insertion Site and Needle Set, page 21]

Figure 27



In Newborns, Infants, and Children, How Deep Should the IO Needle Be Inserted?

Engage the driver trigger and apply moderate, steady pressure. Release trigger when sudden “give” or “pop” is felt, indicating entry into medullary space. A 2010 study with a power-driven IO device confirmed a high reliability in discerning accurate needle set placement by tactile feedback (in models designed to mimic bone density differences).¹ Is There a Risk of Over-Penetration with the EZ-IO Device?

Is There a Risk of Over-Penetration with the EZ-IO Device?

Penetration of the IO needle set through the posterior cortex of the bone is a possible complication, but avoidable with selection of appropriate needle set length and proper insertion technique. As with all vascular access devices, diligent placement confirmation, reassessment of the infusion, site, and limb will assist with reducing risk in cases of potential misplacement.

Is Compartment Syndrome of Concern in Paediatric Patients?

Yes. Compartment syndrome is a serious complication that can result if a large infiltration and/or extravasation goes undetected. The IO insertion site should be monitored frequently for any signs of extravasation or infiltration.

What is the Risk of Injury to the Epiphyseal (Growth) Plate in Paediatric Patients?

Several clinical and preclinical studies have examined potential damage to the growth plate and reported no cases of impaired growth or bone abnormalities in the literature as a result of IO insertion through the epiphyseal plate. [See Effects of IO Access on Growth Plates and Bone Repair for specific studies and in-depth discussion, page 42]

What Can Be Done to Manage IO Infusion Pain in Paediatrics?

Two percent (2%**) intravenous preservative-free and epinephrine-free lidocaine (sometimes referred to as cardiac lidocaine) has been shown to be effective in limiting or alleviating IO infusion pain and may be considered. Lidocaine administered via the IO route for infusion pain should be administered very slowly (over 60-120 seconds) so as to remain in the IO space long enough to achieve a local anaesthetic effect, rather than immediately entering the vascular circulation. More information is available at: www.eziocomfort.com. [See Pain Management for IO Infusion for specific studies and in-depth discussion, page 51]

** 2% intravenous preservative-free and epinephrine-free lidocaine may not be available globally; refer to total dose in milligrams.

Disclaimer

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. The information provided here 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 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 disclaims all liability for the application or interpretation of this information in the medical treatment of any patient.

How Much “Dead Space” Is in the EZ-Connect Extension Set and IO Catheters?

The approximate volume of the EZ-Connect Extension Set is 1.0 ml. The dead space volume of the 15 mm EZ-IO Catheter itself contains 0.03 ml; a 25 mm catheter contains 0.045 ml; a 45 mm catheter contains 0.07 ml. These volumes must be factored into dosing requirements for paediatric patients. The EZ-Connect Extension Set must always be primed prior to attaching it to the EZ-IO Catheter Hub.

For Infants and Small Children, Should the EZ-IO Catheter Be Secured in Any Special Manner?

Yes. The EZ-Stabilizer Dressing is strongly recommended for all patients, but particularly for infants, due to softer, thinner bones in this population. The EZ-Stabilizer Dressing adhesive area can be cut for a better fit on smaller limbs; and should never be placed circumferentially around a limb. For further protection, stabilise the limb with an effective method that limits the likelihood of dislodgement such as an arm board or splint.

Reference:

- 1 Miller L, Philbeck T, Bolleter S, Garcia G. Tactile feedback comparison of three types of intraosseous access devices for needle insertion accuracy. *Ann Emerg Med* 2010;56(3):S133.¹⁵

General Discussion of Intraosseous Access in Paediatrics Including Literature and Technique

The American Heart Association (AHA) and the European Resuscitation Council (ERC) recognises IO access as a viable vascular access route for the paediatric population. The 2010 AHA guidelines for Paediatric Advanced Life Support state: “IO access is a rapid, safe, effective, and acceptable route for vascular access in children. All intravenous medications can be administered intraosseously, including epinephrine, adenosine, fluids, blood products, and catecholamines.”¹ AHA guidelines also emphasise that providers should limit the time spent attempting to establish peripheral venous access in a critically ill or injured child. AHA supports IO or IV vascular access as the preferred route for drug delivery during CPR, and recommends against central venous access as the initial route of vascular access during emergencies.

The ERC recommends consideration of IO access for initial securement of vascular access if intravenous access is difficult or impossible. For paediatric patients in cardiac arrest or pre-arrest states in seriously ill or injured paediatric

patients, the guidelines recommend vascular access by peripheral IV or the IO route. In critically ill children if attempts at peripheral access are unsuccessful after one minute, IO access should be established.² The 2015 ERC guidelines reiterate that IO access is a rapid, safe, and effective vascular access route; and note that the onset of action and time to achieve adequate plasma drug concentrations are similar to that achieved via the central venous route and recommends it as a viable route for drug administration during CPR.

A joint policy statement endorsed by multiple professional societies provided guidelines for care of children in the Emergency Department, included a recommendation for IO equipment in adult and paediatric sizes.³

Medical literature reflects several decades of IO use in paediatric patients. A majority of these references cite the low rate of complications and efficacy of IO vascular access in paediatrics. More information on paediatric IO use can be found in the bibliography available at: <https://www.teleflex.com/usa/en/clinical-resources/ez-io/>

Brief Literature Review

An early (1947) study of 495 paediatric patients undergoing IO procedures emphasized its “great advantage in paediatrics”.⁴ A 1986 article by Iserson et al. discussed successful utilisation of IO access in ten paediatric patients, and described IO access as a safe, rapid method to gain access to venous circulation.⁵

A 1990 New England Journal of Medicine review stressed the relative safety of IO access and reported earlier findings of no lasting negative effects of IO infusion on the bone, growth plates, and marrow elements.⁶ In 2011 the New England Journal of Medicine published an updated overview of paediatric IO access concluding IO access “... is a reliable means of obtaining urgent vascular access in children and is associated with low rates of reported complications.”⁷

A 2005 retrospective study demonstrated the safety and efficacy of IO needle/catheter placement during paediatric critical care transport. Investigators identified 47 patients requiring 58 IO placements; first attempt success rate was 78%.⁸ Complications were noted in 12% of patients, all limited to local edema or infiltration. A second 2005 retrospective study examined data from 129 paediatric major trauma patients who received IO vascular access. The

authors noted that the relatively high mortality rate (64%) was likely due to severity of injuries and difficulty obtaining venous access. Investigators concluded IO access use is safe, simple, and effective, and suggested IO training for personnel involved with paediatric trauma resuscitation.⁹

In a 2008 retrospective study of 95 paediatric patients, Horton and Beamer evaluated the safety and effectiveness of the EZ-IO Device in this population.¹⁰ Successful insertion and infusion was achieved in 94% of the patients; 77% achieved in one attempt. The authors reported four minor complications (4.2%), but none significant. The study conclusions supported use of the EZ-IO Device for children in emergency situations.

A prospective study by Frascone examined prehospital use of the EZ-IO Device in paediatric patients. Successful insertion was achieved in 95% of patients.¹¹ A majority of providers (paramedics, nurses) reported feeling “comfortable” or “very comfortable” with the device, and recommended its use over a manual IO needle. Reported complications included infiltration, slow flow rate, and needle dislodgement during transport. Overviews of paediatric IO vascular access, including three written by anaesthetists describe cases and support IO availability, training, and use in the paediatric population.^{7,12-20}

Multiple paediatric case studies have been cited in the literature. Unique cases include a 2010 case of a two year-old that received hypothermia via IO access; a nine month old treated for suspected cyanide poisoning with IO administered hydroxocobalamin, and a sixteen month old that received scorpion anti-venom for severe distress following a scorpion sting.²¹⁻²³

Effect on Epiphyseal (Growth) Plates

A 1990 New England Journal of Medicine review stressed the relative safety of IO access and reported on earlier findings of no lasting negative effects of IO infusion on the bone, growth plates, and marrow elements.⁶ Lack of negative effect on the epiphyseal plate subsequent to IO infusion has been demonstrated in several radiographic studies in the paediatric population. Preclinical studies in swine have supported similar conclusions. A 1947 clinical study designed to examine incidence of long-term bone abnormalities during radiographic follow-up in seventy-two paediatric patients who received IO insertion. No patient exhibited radiographic bone abnormality and bone growth was normal for all patients in the study. Thirty-six of those patients were

followed up for a year; eighteen were followed for up to two years, and eighteen were followed for over two years post-infusion.⁴ A 1997 study performed radiographic measurements of the tibias in paediatric patients twelve months after IO infusion. Results demonstrated no significant difference in tibial lengths.²⁴ In 2003, a clinical study of paediatric patients receiving IO infusions revealed no radiographic differences in tibia width or length. The follow-up radiographs were performed on average 29 months after infusion.²⁵ A 2003 overview article is also supportive of these findings.²⁶ In 2004, Baren’s summary discussed a study of 23 children that received IO tibial infusions and concluded that long-term growth abnormalities are unlikely in children after IO infusions.²⁷

Site Selection and Landmarks

Identifying and locating appropriate landmarks is essential to successful IO insertion. For step-by-step insertion technique please see section titled “Technique and Training” specific to each insertion site. [See “Selection of Appropriate Insertion Site and Needle Set” on page 21]

Summary of Insertion Technique (after landmarks are located and general technique for all sites)

Insertion: Prior to deploying the driver, ensure at least one black line is visible above the skin when the needle set is touching the bone. Gentle, steady pressure is required for insertion. Due to softer, smaller paediatric bones, special care must be taken during insertion to avoid both excessive pressure and recoil. “Recoil” occurs when the clinician feels the lack of resistance upon entry into the medullary space and inadvertently jerks back on the driver.* Recoil may displace the needle set from the medullary space and prevent additional attempts for IO access at that site. Release trigger when sudden “give” or “pop” is felt, indicating entry into medullary space. A 2010 study with a power-driven IO needle confirmed a high reliability in discerning accurate needle set placement by tactile feedback (in models designed to mimic bone density differences).²⁸

- * **Practice Tip:** An EZ-IO Device training technique developed to avoid too much pressure and the reflex of “recoil” includes practice insertions on a raw egg. This assists with development of the ability to avoid application of too much downward pressure by “letting the driver do the work.” This training also develops the practice of keeping the driver in place once the needle set enters the egg shell.

Stabilisation: After insertion of the EZ-IO Catheter, use the EZ-Stabilizer dressing to secure the device and prevent accidental dislodgement. The EZ-Stabilizer dressing can be cut to size, and “telescopes” to accommodate varying insertion depths. Generally, the EZ-Stabilizer dressing should not be placed circumferentially around an extremity. If an EZ-Stabilizer dressing is unavailable, other methods should be used to secure the device. For further protection, we strongly recommend securing the leg with an arm board or splint; and the arm with an effective securement device to limit potential for dislodgement (such as a sling and swathe or a shoulder immobiliser brace).

Syringe Flush: Infants and small children will not be able to accommodate the same syringe flush volume and force as recommended for adults and may require less force for both the syringe flush and infusion of fluids. Clinical judgment should be used to determine an appropriate volume for the syringe flush and infusion pressure in paediatric patients, and will be dependent on the child’s condition, weight, and size. A general flush volume recommendation is 2-5 ml for infants and small children. The flush should generally not be done as rapid or as vigorously as in an adult, because the pressure generated could cause the needle to become dislodged from the intended insertion site/depth, since paediatric bones are much softer than that of an adult.

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 catheter 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)
2. Flush IO catheter with normal saline
 - Adult flush: 5-10 mL
 - Infant/Child flush: 2-5 mL
3. Slowly infuse lidocaine (half of initial dose) over 60 seconds
4. Attach extension set primed with normal saline and flush

- Repeat PRN. Consider systemic pain control for patients not responding to IO lidocaine.

Confirm Placement: Correct IO placement should be confirmed with the following methods:

- Stability of catheter
- Ability to aspirate blood or marrow*
- Adequate flow rate

* An inability to aspirate is sometimes described after initial IO catheter insertion. Inability to withdraw/aspirate blood from the catheter hub does not mean the insertion was unsuccessful. Consider attempting to aspirate after a small flush.

Infusion: Infants and children may require less infusion pressure (than adults) for adequate flow rates.

Monitor Site: The IO insertion site and affected limb must be monitored frequently for extravasation or other problems such as an increase or new complaint of pain, inability to infuse, changes in skin color, or anything that may indicate the IO insertion site and infusion may be compromised.

For additional guidance on IO use in infants and children, please contact Teleflex Customer Support at 1.866.479.8500 or +1.866.479.8500 out of the US, your local Teleflex representative or visit: <http://www.teleflex.com/ezioeducation>.

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Laboratory Analysis/Blood Sampling

Are Blood Specimens Drawn Via the IO Route Adequate for Laboratory Analysis?

The most recent clinical studies in healthy volunteers examining IO compared to venous laboratory values demonstrated significant correlation for many commonly ordered lab studies, with some exceptions noted. In these studies, IO blood proved to be reliable for:

- Red blood cell count
- Haemoglobin and haematocrit
- Glucose
- Blood urea nitrogen (BUN)
- Creatinine
- Chloride
- Total protein
- Albumin
- Lactate

Significant correlation was not achieved for sodium, potassium, CO₂, calcium, platelets or white blood cell count. However, sodium and potassium values were clinically similar. [See Laboratory Analysis/Blood Sampling from IO Access on following page for research details.]

From a review of all known published clinical literature examining IO compared to venous laboratory values, the list below summarises aggregate results of IO correlation with IV blood values.

The following laboratory values have produced significant correlation between IO and IV values in human studies:

- Glucose
- Hemoglobin
- Hematocrit
- BUN
- Creatinine
- Total protein
- Red blood cell count
- Albumin
- Chloride

The following laboratory values have shown mixed results in producing significant correlation between IO and IV values (some values were clinically similar, but not statistically correlated):

- CO₂
- Potassium
- Sodium
- Calcium
- Platelet count
- Phosphorus
- Uric acid/urea
- Total bilirubin
- SGOT
- LDH
- Alkaline phosphatase
- Bicarbonate
- pH
- pO₂ (venous values)
- pCO₂ (venous values)
- Base excess

IO and IV values for white blood count do not correlate in any known study.

Laboratory Analysis/Blood Sampling from IO Access

Based on preclinical and clinical evidence comparing IO and venous or arterial sources a number of common laboratory values correlate well; other values show clinical similarity without statistically significant correlation, therefore caution should be exercised with their interpretation. Certain point of care analysers have been studied with acceptable results. Check with your laboratory for IO specimen processing capabilities. For more information regarding IO lab analysis, refer to: www.teleflex.com/ezioeducation.

Summary and Recommendations

Overall review of the clinical evidence suggests that early in the resuscitation process, blood gas values derived from IO blood may be used to assess central venous acid-base status, and that a number of blood count and chemistry values will equal venous samples. Other values will approximate venous values; few will not correlate. IO samples should be used with caution after resuscitation efforts beyond the immediate phase. The work of Brickman et al. provides evidence that blood typing and screening can be done accurately and reliably using IO blood.⁹ For a tabular summary of laboratory values that have produced statistically significant correlation between IO and IV in human studies, refer to previous section.

Clinical Studies

A small prospective pilot study by Tallman was published in 2016 using a point-of-care analyser to compare samples from IO and venous samples in the emergency department. With consideration of the study limitations (small subject numbers, inability to obtain venous samples from some patients, limited testable analytes amongst those noted) investigators felt the results were clinically acceptable for pH, bicarbonate, sodium and base excess, and possibly lactic acid.¹

A prospective study compared IO and venous laboratory values obtained from a point-of-care analyser (i-STAT) in 20 children. IO blood specimens were collected from the iliac crest; 2 ml were discarded before the sample was collected for analysis. Results showed differences between venous and IO sample were clinically acceptable for pH, base excess, sodium, ionised calcium, and glucose in haemodynamically stable patients. Authors concluded that analysis of IO samples with a bedside point-of-care analyser is feasible and in emergency situations may be useful to guide treatment.²

From a series of healthy volunteer studies conducted in 2012 and 2013, Montez et al. compared IO and venous blood to determine if there is a clinical similarity and/or correlation between samples from the two sources for serum lactate level. From each arm of 15 study subjects, peripheral venous specimens were collected, followed by a proximal humerus IO blood sampling. Each IO and venous sample was analysed for lactate levels, using the I-Stat point-of-care analyser. There was a positive correlation between IO blood lactate and venous blood lactate (R²=0.623, n=23, p<0.001). Investigators concluded that lactate levels obtained from IO blood appear comparable to lactate levels from venous blood, and those values are reflected in positive correlation. The subjects in this study were healthy and results may not accurately reflect the results that may be seen in patients who are septic or have other illnesses and injuries. Further investigation is needed in patients to determine if the relationship between IO and IV values continues to exist in non-healthy patients.³

A 2009 study (unpublished) in healthy volunteers examined the reliability of IO cardiac enzyme and blood gas values.⁴ The study compared venous and IO samples of two common cardiac enzymes (Troponin-I and creatine phosphokinase), and also compared venous, arterial and IO samples for blood gas analyses. Values for IO blood gases fell between arterial and venous blood sample values. Results demonstrated a significant correlation between venous and IO blood for creatine phosphokinase, and for pH and base excess. Arterial and IO blood correlated well for pCO₂. Correlation analysis was not possible for Troponin-I. However, results were identical or clinically similar for seven of the ten samples.

A study using adult volunteers conducted in 2009 examined the relationship between IO and venous blood samples for complete blood count and chemistry profile.⁵ Researchers concluded that IO and IV laboratory values had statistically significant correlation for many commonly ordered lab studies, with some exceptions noted. The IO space proved to be a reliable source for red blood cell count, haemoglobin and haematocrit, glucose, blood urea nitrogen, creatinine, chloride, total protein, and albumin. No statistically significant correlation was achieved for sodium, potassium, CO₂, calcium, platelets or white blood cell count. However, sodium and potassium values were clinically similar.

A 2000 study by Hurren examined IO blood samples for routine blood analysis in paediatric patients.⁶ The laboratory values for haemoglobin, haematocrit, sodium, urea, creatinine, calcium were considered to be clinically similar. Potassium levels were elevated in most samples, and study authors recommended “great caution should be exercised in their interpretation.” Authors also recommended that blood samples obtained intraosseously may give a useful guide to peripheral blood levels of some haematological and biochemical values, but cautioned the values should be “interpreted with care.”

In 1994, Ummenhofer and associates found bone marrow and venous blood samples to be similar in regard to haemoglobin, sodium, chloride, glucose, bilirubin, BUN, creatinine, pH, and bicarbonate in 30 children with blood disorders.⁷ IO blood was also moderately accurate for haematocrit, potassium, and total protein, but not for alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase, thrombocytes, pCO₂, pO₂, and leukocytes.

In a 1991, 15-patient study, Grisham and Hastings reported that bone marrow aspirate from the iliac crest was a reliable source for blood gas and serum chemistries.⁸ In a 28-patient clinical trial the following year, Brickman et al. compared IO aspirates against standard peripheral IV blood with regard to ABO and Rh typing.⁹ Researchers concluded that IO blood can be used for accurate and reliable typing and screening of blood. Their study did not address whether IO blood can be used for cross-matching.

Preclinical Studies

In 1986, Unger and associates reported that electrolytes, calcium, glucose, BUN, and creatinine were not different in bone marrow and venous blood in swine.¹⁰ In a 1989 canine study, Orłowski et al. compared blood laboratory values for IO, arterial, and venous samples. No significant differences were found among the three source sites for most blood electrolytes, chemistry values, and haemoglobin. Results for liver enzymes (lactate dehydrogenase, alkaline phosphatase) varied among the three sites. Blood gases were significantly different among all sites, pH, pO₂, pCO₂, HCO₃, and SpO₂ were consistently intermediate between arterial and venous samples, suggesting a possible correlation with arterIALIZED capillary blood gases.¹¹ In the 1990s, Kisson and associates conducted a series of swine studies to determine the relationship between IO and venous blood for determining acid-base values. In a 1993 study the authors reported that acid-base status of IO blood is similar to status of central venous blood, and may be

an acceptable alternative to central venous blood gas values in determining central acid-base status during CPR.¹¹ In a 1994 study comparing pH and pCO₂ values of samples simultaneously obtained from central venous and IO lines, researchers concluded that pH and pCO₂ values were similar.¹³ In a 1997 study, Kisson’s group compared the acid-base values of blood obtained through the IO route and mixed venous blood. The authors concluded that IO blood may reflect local acidosis, yield lower pCO₂ and higher pH values than central venous blood as CPR progresses.¹⁴

A 1999 study by Abdelmoneim et al. examined the acid-base status of blood samples from IO and mixed venous sites during prolonged CPR and drug infusions in swine.¹⁵ The investigators found no difference in pH and pCO₂ levels during the first 15 minutes of CPR. However, this correlation did not continue during resuscitations of longer duration or after bicarbonate infusion. Large volumes of saline infusion and the use of epinephrine did not affect the association in resuscitation times under 15 minutes.

In another 1999 swine study, Johnson et al. found no differences in sodium, potassium, magnesium, lactate, and calcium levels in IO aspirates versus central venous blood samples during the first five minutes of CPR.¹⁶ After 30 minutes, differences were noted in magnesium and potassium values, but the investigators observed no differences in biochemical (i.e. chemistry values) and haemoglobin values if no drugs were given though the intraosseous site.

In a 2011 preclinical study by Strandberg et al., IO and arterial blood samples were collected over a six-hour time period from the tibia of an anaesthetised swine and analysed using an i-STAT device to compare values. Results showed compliant values between IO and arterial blood for electrolytes, haemoglobin, pH, and pCO₂. Lactate, base excess (BE), PO₂ and SO₂ were less compliant. There were high correlations between SO₂ and PO₂ although the levels in arterial blood were higher.¹⁷ The same investigator published a 2012 preclinical study with a similar design collecting blood samples from bilateral tibial intraosseous cannulae and an arterial catheter over six hours using an i-STAT point of care analyser. Authors noted analysis of intraosseous samples with a handheld cartridge based system is convenient and should bypass the potential problem with bone marrow contents damaging conventional laboratory equipment. For most variables, there seemed to be some degree of systematic difference between intraosseous and arterial results; and the direction of the difference seemed to be predictable. Investigators concluded that cartridge based point of care

instruments appear suitable for the analysis of intraosseous samples. The agreement between intraosseous and arterial analysis seemed to be clinically useful.¹⁸ In another swine study, several of the same investigators sought to evaluate whether intraosseous blood samples can be used to measure opioids, and if so, to determine the level of accuracy of those measurements. Blood samples were drawn from bilateral tibial IO catheters and from a central venous catheter for six hours. The morphine levels in the CVC samples were higher than those drawn from the IO sites; and authors postulated that morphine has low fat solubility and young swine marrow is rich in fat which may have contributed to the difference in levels. Between IO sites the variability between the two IO ports was less than 10%. The authors concluded intraosseous samples can be used for the analysis of morphine if an IV route is not available.¹⁹ Eriksson et al. conducted a preclinical study in which eight anaesthetised swine were put into an induced septic shock state to allow troponin I level measurements to be compared from serial venous plasma, arterial plasma, and intraosseous aspirate specimens collected hourly. Two milliliters of IO aspirate were discarded before collecting each IO specimen for analysis. The levels of IO troponin I increased during the first three hours of shock but then plateaued at a high level while the venous and arterial levels continued to increase. Authors concluded that troponin I can be analysed in bone marrow aspirates in a shock model and that this information may be useful in medical emergencies where cardiac damage is suspected to be involved.²⁰

In 2016, Eriksson compared arterial and intraosseous derived biomarkers to determine if the results would correlate well enough over a period of six hours to consider use of IO derived blood when traditional samples are difficult to obtain. Authors noted there were no clinically relevant average differences between IO and arterial samples for alanine aminotransferase, alkaline phosphatase, aspartate aminotransferase, creatinine kinase (CK), and gamma-glutamyl transferase values; and IO blood may be good enough for initial estimates of these markers in emergencies. However the lactate dehydrogenase levels showed less correlation and for certain tests, the precision of IO samples may be limited.²¹

In Strandberg’s 2016 swine study IO and venous samples were analysed for thromboelastography (TEG), prothrombin time (PT), activated partial thromboplastin time (APTT), and fibrinogen concentration. The IO samples were clinically hypercoagulable, rendering some samples unevaluable; clinically relevant differences were observed for APTT but not for PT and fibrinogen and the TEG demonstrated a shortened

reaction time. The ability to use IO drawn blood for coagulation studies may be limited.²²

In 2016 a preclinical swine model study was conducted to compare blood samples drawn from a central venous catheter (CVC) to blood samples drawn from IO catheters. This pilot study had two objectives: determine how long an infusion must be stopped before drawing an IO specimen for analysis; and to determine if there is a difference between IO specimen results when the first 2 ml of IO blood were discarded and not discarded. An i-STAT Handheld point of care (POC) analyser (Abbott Laboratories) was used to evaluate for sodium, potassium, chloride, TCO₂, anion gap, ionised calcium, glucose, urea nitrogen (BUN), creatinine, hematocrit, and hemoglobin. All blood samples were drawn and placed into green top laboratory tubes containing sodium heparin and later the blood was placed into the sample cartridges for analysis. Once initial access was obtained, a baseline sample was obtained at approximately the same time from all access points. For a comparison of IO samples pre- and post- 2 ml discard, the initial 2 ml IO sample was aspirated; then a subsequent 2 ml sample was collected. For the post-infusion wait study, a five minute infusion of normal saline was started to the IO sites and then stopped. The initial post-infusion wait period was five minutes. Time intervals were reduced and results compared to baseline were similar with as little as one minute wait time. A target wait time of two minutes was chosen to stay similar to wait time recommendations in IV lab studies. Authors concluded that if IO vascular access is necessary, and POC samples requested for these specific lab values, the initial specimen drawn from the IO catheter may be considered for sampling. Also, if an IO infusion of saline is occurring, a wait time of two minutes post-stopping the infusion may be adequate for analysis. For these analytes, IO specimen values were comparable to CVC values. Limitations include swine model, sample size, and infusion of one solution. This study is not yet published.²³

Technical Considerations

Most of the reported study data was based on IO laboratory specimens obtained prior to any infusions or flush, therefore results may differ from samples obtained post-infusions.

It is important to check with your laboratory for specimen processing capabilities. Blood samples for laboratory analysis can be drawn from the EZ-IO Catheter by connecting a syringe directly to the EZ-IO Catheter Hub. (Note: the only times a syringe should be connected directly to an EZ-IO Catheter Hub is for drawing laboratory samples, for administration of medications that require very small fluid volumes for precise doses to infants and small children, or for catheter removal). For most laboratory studies, the first 2 ml should be aspirated and discarded prior to withdrawal of laboratory samples. If necessary (e.g. paediatrics), the first 2 ml may be saved for certain tests, such as blood typing or blood cultures.^{9,EO} Aspiration of adequate volumes for laboratory samples may vary greatly between patients; and IO blood samples clot more rapidly than venous samples. Therefore, samples should be prioritised in order of importance.

Consider drawing initial blood samples into smaller volume syringes, and placing them immediately into sample tubes. Point of care (POC) analysers may more easily process IO samples (for available parameters) as they require less volume. Samples must be identified as IO blood so laboratory personnel can determine the suitability of equipment for IO blood lab processing; and accurately interpret results based on the possible presence of stem cells not found in peripheral blood; or cell counts that are known to differ between IO derived blood samples and those from arterial or venous sources.

Questions about the use of results from intraosseous access-derived blood samples were raised in 2008 in two editorial letters; and again in a 2014 letter by Cervinski. Nicoll mentioned possible incompatibilities between the available laboratory analysers with IO blood that could result in blockage.²⁴ The recommendation was that laboratory tests only be carried out on either arterial or femoral venous samples during resuscitation. In a letter supporting use of IO derived blood samples, Dr. Salter responded with research supporting several laboratory parameters and stated IO samples were a “legitimate” technique that could guide care especially in consideration of the time delay in gaining venous or arterial access; and stated that IO samples should be appropriately labelled.²⁵ Cervinski’s 2014 letter includes a brief review of the literature, discusses the limitations associated with studies on IO derived blood samples, and recommends IO blood may only be useful in cases of suspected overdose for toxicology.²⁶ A 2015 article discusses use of bone marrow aspiration fluid using automated blood cell counters and the potential advantages and limitations of this practice. Amongst the key points are bone marrow fluid can be used as a substitute for venous blood in emergency situations, at least for the measurement of red cell parameters; and the complexities of the comparison between the composition of blood aspirated from bone as “bone marrow fluid” compared to peripheral blood, for which most instruments were designed, create difficulties when assessing for haematology.²⁷

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Induced Hypothermia by Intraosseous Access

The 2010 Guidelines from the American Heart Association include recommendations for therapeutic hypothermia. One method of inducing therapeutic hypothermia (TH) includes vascular administration of chilled fluids.¹

A 2007 article described successful use of the EZ-IO Device for induction of therapeutic hypothermia at an urban EMS service. For the observed period, paramedics administered chilled saline for post-resuscitation induction of hypothermia in 68 patients. The IO route was used alone or with a peripheral IV line in 74% of the TH cases.²

Truhlar et al. described use of the EZ-IO Device to induce therapeutic hypothermia (post-resuscitation) in a two year-old paediatric patient. The patient survived and was ultimately discharged home without neurological consequences.³

Though there have been case reports on therapeutic hypothermia induction via the IO route, there have been no clinical studies evaluating the effects of chilled fluids on the bone marrow.⁴

Preclinical Studies

In a 2007 published study in swine, investigators concluded that mild therapeutic hypothermia can be effectively induced after successful resuscitation of prolonged ventricular fibrillation through infusion of chilled saline via the IO catheter.⁵

A 2011 swine study compared the efficacy of chilled saline administration between the IO and IV routes.⁶ Endpoints were brain, esophageal, and rectal temperatures digitally recorded after a 45-minute infusion of chilled normal saline. The results suggested no clinical or statistical difference between IV and IO routes for infusion of chilled saline for therapeutic hypothermia and the ability of the two routes to facilitate reduction of core temperature.

Another 2011 swine study concluded the peripheral IV route was superior to IO for induction of therapeutic hypothermia.⁷ The total infusion volume of chilled saline in the IV group was approximately 2.5 times that of the IO route and there was a significantly slower infusion rate for the IO route in this study.

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Special Considerations

Can the EZ-IO Catheter Remain in Place during a CT Scan?

There are no known reports of problems associated with inserted IO catheters during computed tomography (CT). If an IO catheter is placed in the proximal humerus, the affected arm should be secured in the adducted position (with the arm at the patient's side). An IO catheter may cause slight scatter artifact on the images obtained.

Can the EZ-IO Catheter Remain in Place during an MRI Scan?

No. The EZ-IO Needle Set is made of 304 stainless steel, and should not be present during MRI procedures. The metal in the EZ-IO Catheter could potentially be problematic if subjected to high magnetic forces.

Can the EZ-IO Needle Sets Be Used in Patients with Osteoporosis?

Yes. The combination of the needle set design and rotation of the EZ-IO Device achieves intraosseous access with little disruption of bone architecture during the insertion process. The EZ-IO Device results in a precise hole in the bone, requires minimal force for insertion, and provides greater control than a needle set manually rotated into bone.¹ See Figure 28a.

Note: Use of the EZ-Stabilizer Dressing is strongly recommended for additional stabilization as the weaker bone structure may increase chance of needle set dislocation. Reevaluation is especially important in this patient population also.

* Osteoporosis is a contraindication for the sternal insertion site with the EZ-IO T.A.L.O.N. Needle Set

Should an IO Device Be Inserted in the Humerus on the Same Side as a Mastectomy?

It is recommended that proximal humerus IO insertion be avoided on the affected (post-mastectomy) side if possible, but it is not an absolute contraindication.^{E0}

Is IO Access Contraindicated in a Patient with Avascular Necrosis?

By definition, a patient with avascular necrosis lacks adequate vasculature at the affected site. While not contraindicated, IO access should be avoided at the avascular site, and an alternative insertion site should be selected.^{E0}

Is IO Access Contraindicated in Osteogenesis Imperfecta?

While osteogenesis imperfecta is not an absolute contraindication for IO use, the degree of osteogenesis imperfecta may present challenges to IO vascular access. The soft bones of an osteogenesis imperfecta patient may prevent the IO catheter from maintaining an adequate seal for infusion. It may also be difficult or impossible to adequately stabilise an IO catheter in a patient with osteogenesis imperfecta. There is one known case regarding IO vascular access in an osteogenesis imperfecta patient. A 2009 article describes the case of an adult male in cardiac arrest requiring emergency vascular access. Several IO attempts resulted in the IO catheters immediately becoming loose, and the inability to secure or flush the IO devices. It was later determined that the patient suffered from Type III osteogenesis imperfecta, a more severe form of the disease.²

Can an IO Device be Used In Burn Patients?

Yes. An IO device can be inserted through burned skin as long as the underlying bone has not been compromised.³ It is important to be aware that swelling due to post-burn edema may be severe enough to affect the stability of the IO access site so frequent reevaluation for signs of dislodgement is important.

Can the EZ-IO Device Be Used In Hyperbaric Medicine?

The driver's performance and electrical compatibility within the hyperbaric chamber has not been tested and there is no data to support its use in that clinical setting. Under normal circumstances, vascular access is obtained prior to entry into the hyperbaric chamber; however, if the need to obtain IO vascular access arises in the chamber, a manual insertion is recommended due to the risk of spark in an oxygen-rich environment. There is no contraindication to IO infusion in the hyperbaric chamber.

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Research



Image of bone, post-EZ-IO Catheter insertion



Image of bone post IO access using impact-driven device

Has Research Been Conducted Demonstrating the Safety and Efficacy of IO Vascular Access?

The body of research regarding intraosseous vascular access is extensive. The safety and efficacy of IO access has been studied in a variety of clinical environments worldwide. Clinical literature includes over 500 articles describing IO access (referred to as "bone marrow" access in early literature from the 1920s). Teleflex has compiled an extensive IO bibliography of published articles and studies. This bibliography is available online at:

<https://www.teleflex.com/usa/en/clinical-resources/ez-io/>

Facts related to intraosseous vascular access in published literature (as of Oct 2018):

- Over 940 articles describing intraosseous vascular access
- More than 320 articles (in six languages) regarding use of the EZ-IO Device
 - Approximately 97 articles describing case studies or clinical trials
 - Over 5,500 patients included in research studies

How Does the EZ-IO Device Compare with Other IO Products?

All IO vascular access products are designed to deliver fluids and medications through the IO space. Devices fall into three basic categories: manual, impact-driven/spring-loaded, and semi-automatic devices. The EZ-IO Device is the only battery-powered device on the market. Several research studies and review articles have examined comparative clinical data among various IO devices on the market.¹⁻⁴

The specially designed cutting EZ-IO Needle Set and powered driver enables clinicians to have better control of insertion with tactile feedback when compared with manual or spring-loaded/impact devices.⁵⁻⁶ The photographs in Figures 28a and 28b demonstrate the symmetrical cutting tip of the EZ-IO Needle Set (Figure 28a) provides a more precise entry hole into the medullary space which may minimise the risk of extra-vasation when compared to the hole created by a spring-loaded impact driven IO device (Figure 28b). Figures 28a and 28b show a microscopic view of bones following IO insertion. There was no extravasation of the blue dye injected after placement of the EZ-IO Catheter, and no microscopic fractures, as seen with use of the spring-loaded impact device.⁵

The EZ-IO Device helps prevent over-penetration of the bone by allowing the clinician to immediately stop the procedure by releasing the driver trigger when the sensation of the change from the hard outer bone cortex to softer cancellous bone is felt. A 2010 study with a power-driven IO needle set confirmed high reliability in discerning accurate needle set placement by tactile feedback (in models designed to mimic bone density differences).⁶

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Teleflex Customer Service

Is there someone available at Teleflex to provide assistance?

Yes. Our support staff includes physicians, nurses, paramedics, educators, and engineers. All calls made in the US are toll-free. You may also go to teleflex.com/ezioeducation for more region specific information.

Clinical Questions:

24 hours a day, 7 days a week

- Clinical support in US: **800.680.4911**
- Clinical support outside US: **+1.800.680.4911**

Technical Questions:

Monday-Friday 8:00 am – 5:30 pm EST/CDT

- Customer service in US: **866.479.8500**
- Customer service outside US: **+1.866.479.8500**

Where should EZ-IO Device problems (or complications) be reported?

- Complications should be reported to Teleflex at the earliest possible time. Please use the Customer Service number: **866.479.8500** or 24-hour emergency number: **800.680.4911**
- Teleflex can also answer questions and provide guidance regarding U.S. FDA reporting and compliance

Is there more information available on the EZ-IO Device (e.g. training, specifications)?

Teleflex provides multiple resources:

- On-site training with expert clinical staff
- Clinical and Medical Affairs, including a dedicated research team, Global Research, and Scientific Services. Questions may be directed to: Clinical.Affairs@teleflex.com
- Ready-to-use training presentations
- Training videos
- Online training documents
- Frequently asked questions/Discussion topics on IO
- 24/7 clinical support
- Teleflex web site (www.teleflex.com)

If additional assistance, or answers to specific questions are needed, please call Customer Service (toll-free in US): **866.479.8500** (Outside US: **+1.866.479.8500**).

