Original Issue

FEEDBACK TO THE FIELD (FT2F) #17:

Intraosseous Intravenous (IO-IV) Device Use

AFMES: COL(Ret) H.T. Harcke, MC, USA*

Lt Col E. Mazuchowski, USAF, MC

DHA MED LOG: CDR T. Brunstetter, MSC, USN

Capt G. Diaz, USAF, BSC

S. Hart, RN, BHSP

S. Burrows, Biomedical Electronic Technician

*American Registry of Pathology in support of AFMES

DISCLAIMER

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BACKGROUND

IO-IV Devices have been showed to be effective in combat casualty care.

Medical personnel show a high success rate for placement of devices in the sternum and proximal tibia.

The EZ-IO® needles are the commonly used devices for humeral and tibial placements.

COMBINED DATA* Sternal and Tibial IO-IV's

Location	In	Out	Total
Sternum	78	20	98
Tibia	58	3	61
Total	136 (86%)	23 (14%)	159

*Harcke HT, Crawley G, Ritter B, Mazuchowski E: Feedback to the Field: An Assessment of Sternal Intraosseous (IO) Infusion. J Special Operations Medicine,Vol 11, Ed 1:23-26, Winter 2011

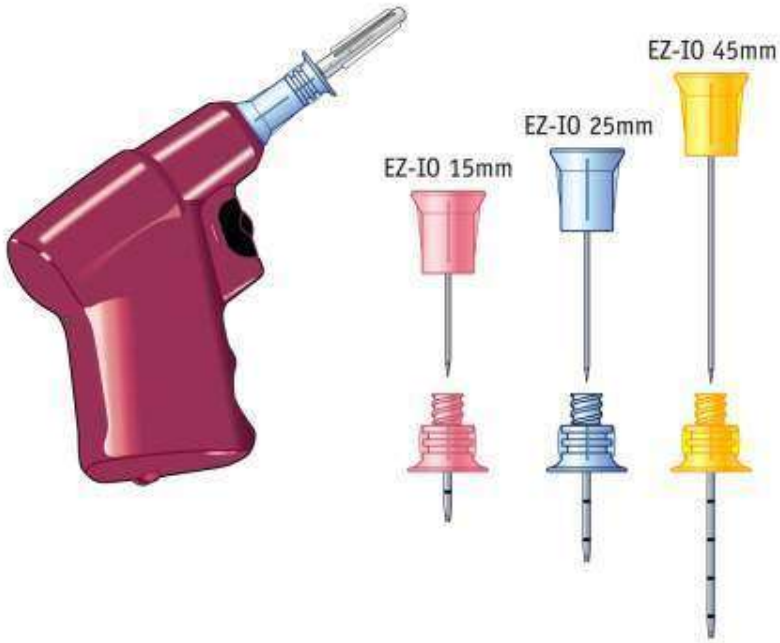
*Harcke HT, Crawley G, Mabry R, Mazuchowski E: Placement of Tibial Intraosseous Infusion Devices. Mil Med 176:824-827, 2011

EZ-IO® IO-IV devices may be inserted with a power driver (drill) or manually.

EZ-IO

1. EZ-IO® 15mm (3-39 KG), EZ-IO® 25mm (40 KG AND GREATER) AND EZ-IO® 45mm (EXCESSIVE TISSUE)

DEVICE DESCRIPTION: EZ-IO Needle Sets are comprised of a Safety Cap, a Stylet and a Catheter. When the Stylet is removed a standard Luer lock is exposed. Needle Sets are made of 304 Stainless and Catheters are 15 gauge. Needle Sets are provided sterile, non pyrogenic and in protective packaging. Needle Sets are intended for use with the EZ-IO Power Driver (Figure 1).



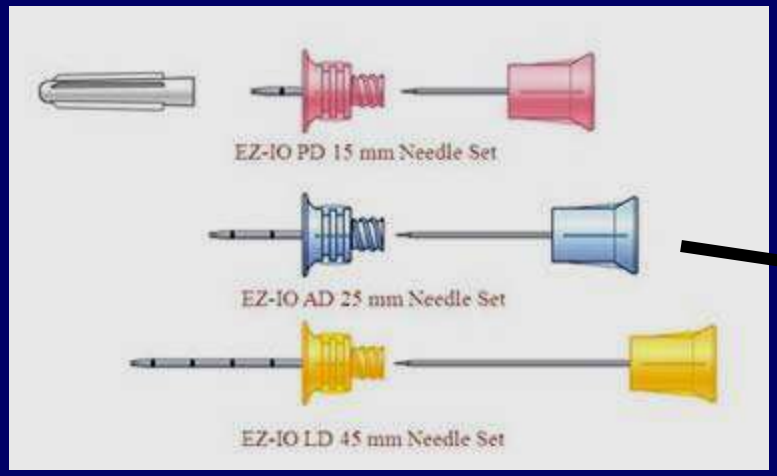
EZ-IO Power Driver and Needle Sets (FIGURE 1)

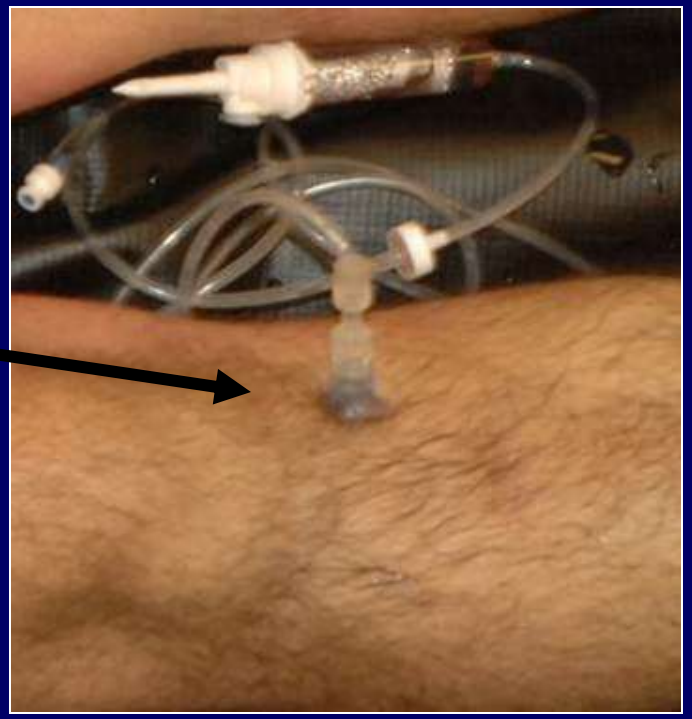
The 25 mm (blue hub) and 15 mm (pink hub) needles may be inserted manually.

The 45 mm (yellow hub) requires a power drill for insertion and does not come with a manual driver.

Tibial IO-IV

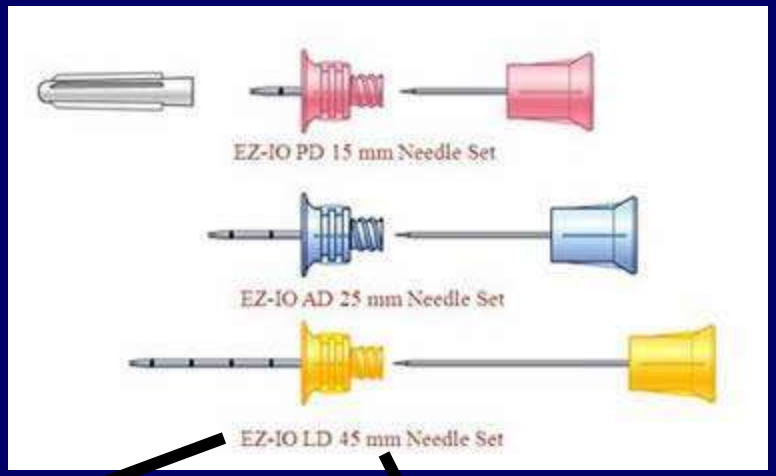
Standard placement is in the medial aspect of the proximal tibia with the 25 mm blue hub needle set.





Humeral IO-IV

Standard placement: proximal anterior or lateral humerus using 45 mm yellow hub needle set.



The manufacturer indicates the 15 mm pink collar needle set was developed for pediatric use (patients 3-39 kg).

Comprehensive Protocol Development Guide *

INDICATIONS:

EZ-IO® 25mm (40 kg and over) & EZ-IO® 15mm (3–39 kg) EZ-IO® 45mm (40 kg and over with excessive tissue)

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

* www.vidacare.com/files/EZ-IO-Combined-Protocol-T-445RevD-10-14-10.docx

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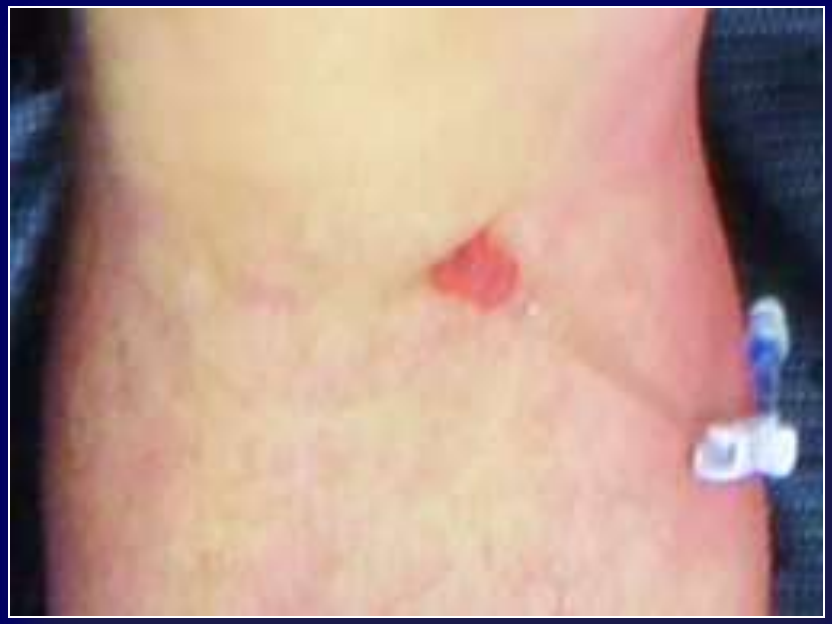
RECENT OBSERVATIONS

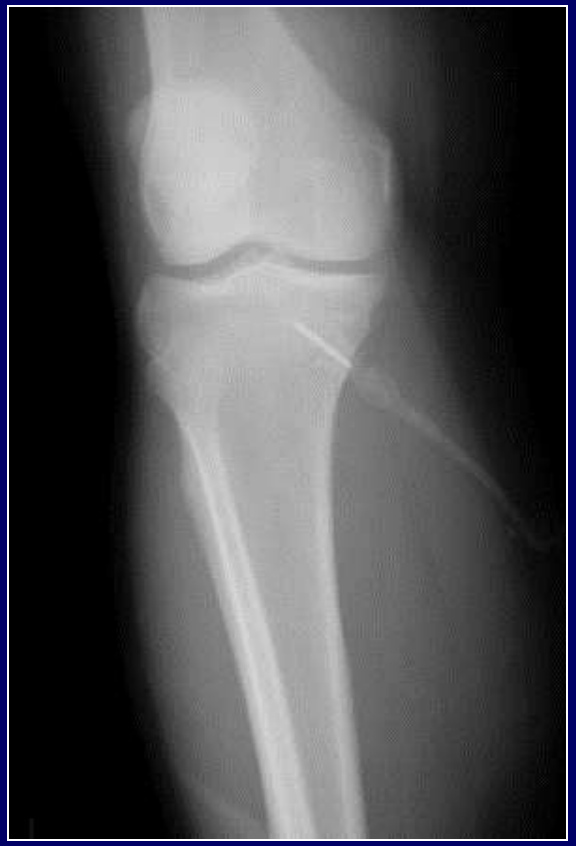
In a small number of unsuccessful IO-IV placements using EZ IO® needles it appears that optimal length needle was not selected.

In determining which needle to use, the depth of tissue overlying the bone and the distance needed to adequately pass into medullary bone should be considered.

CASE STUDY # 1:

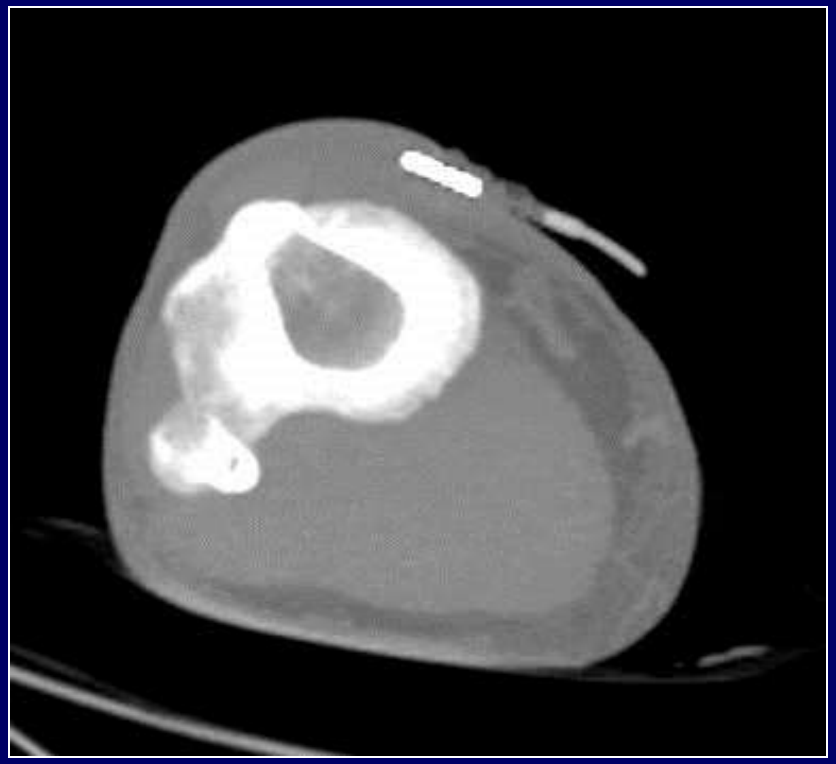
Attempt made to place an IO-IV in the proximal right tibia. Note that the plastic hub of the needle is pink.

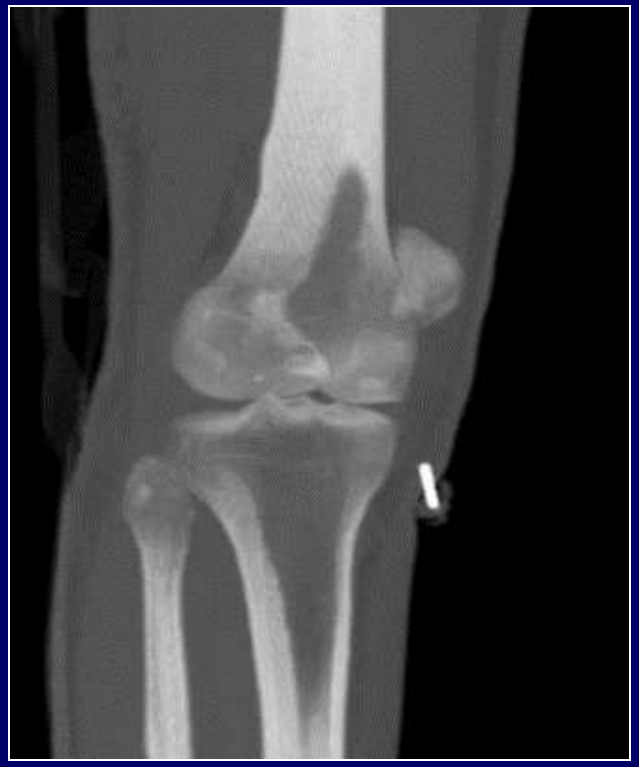




CASE STUDY # 1:

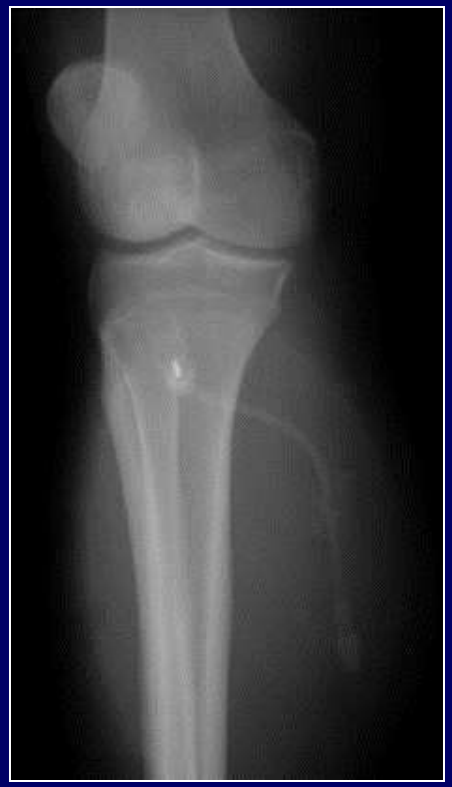
Axial and coronal CT show that the needle is not in bone.

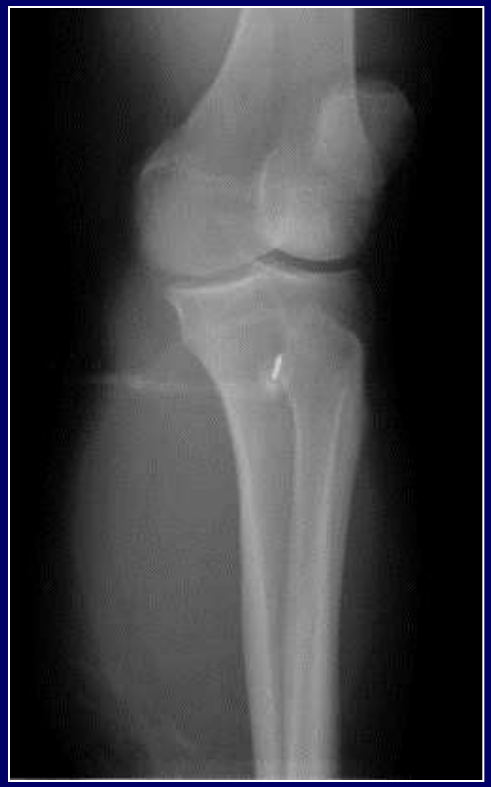




CASE STUDY # 2:

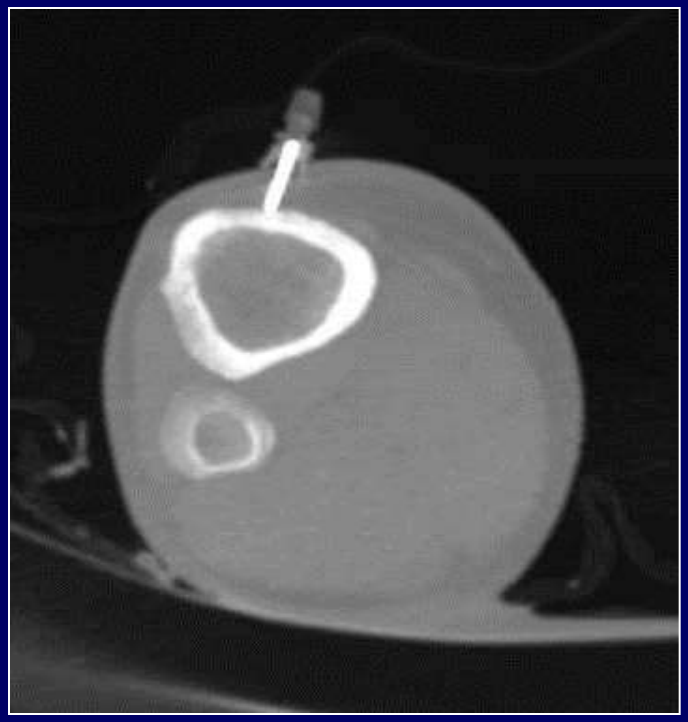
Attempts made to place IO-IV's in the proximal tibias. Note that the plastic hub of the right needle is pink and the hub of the left needle is blue.

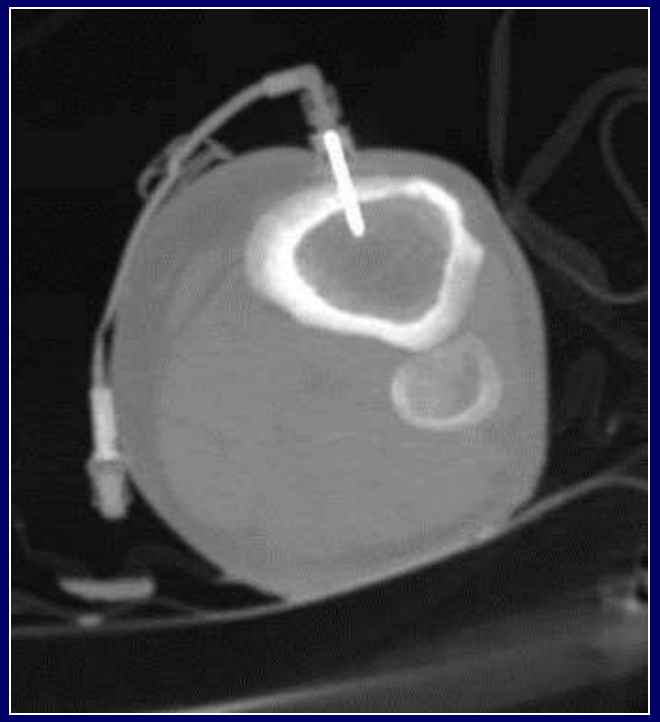




CASE STUDY # 2:

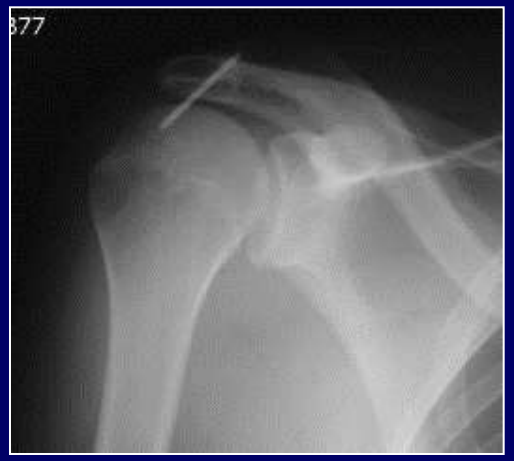
Axial CT shows the right tibial needle (pink hub) does not penetrate the bone cortex, the left tibial needle (blue hub) is in medullary bone.

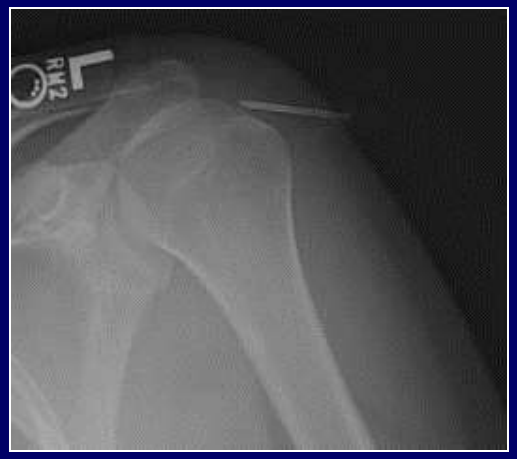




CASE STUDY # 3:

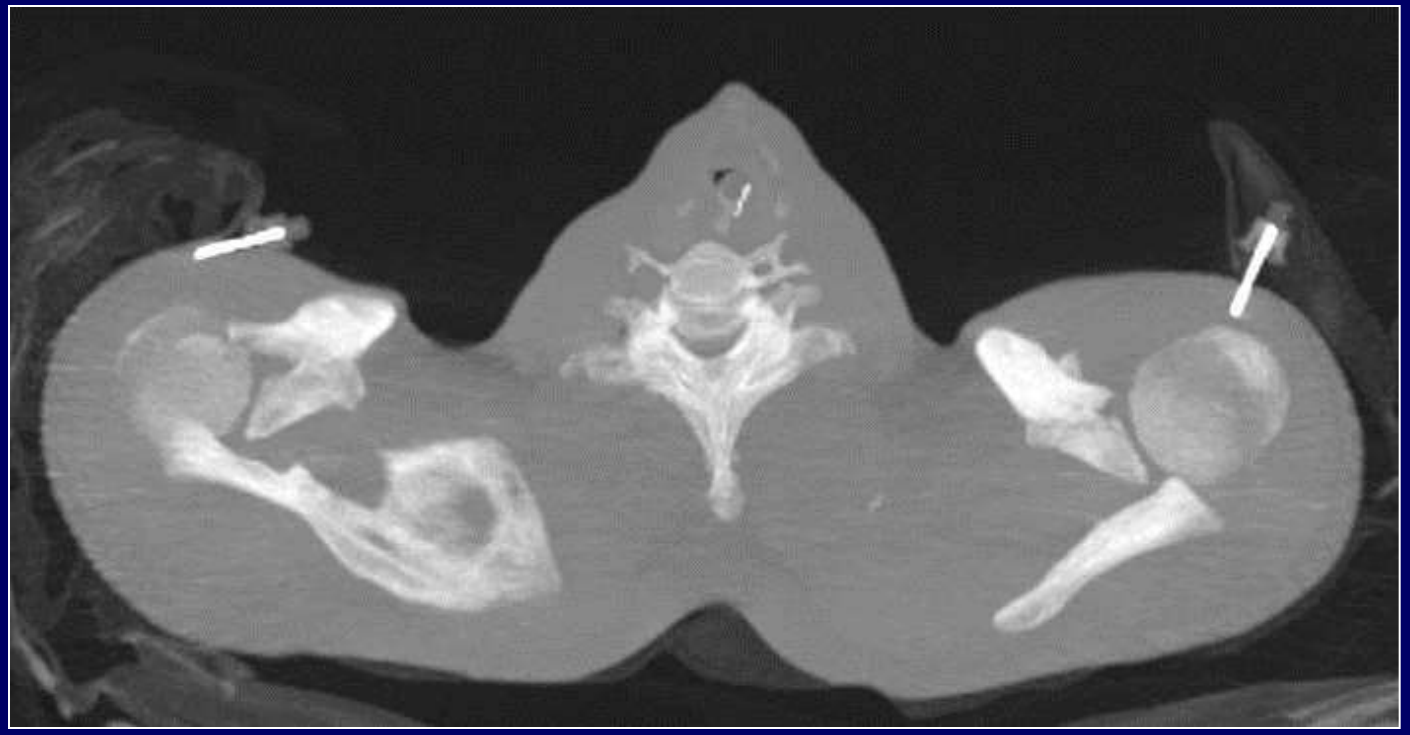
Three (3) attempts made to place IO-IV's in the proximal right (1) and left (2) humerus. Note that the plastic hubs of the needles are blue.





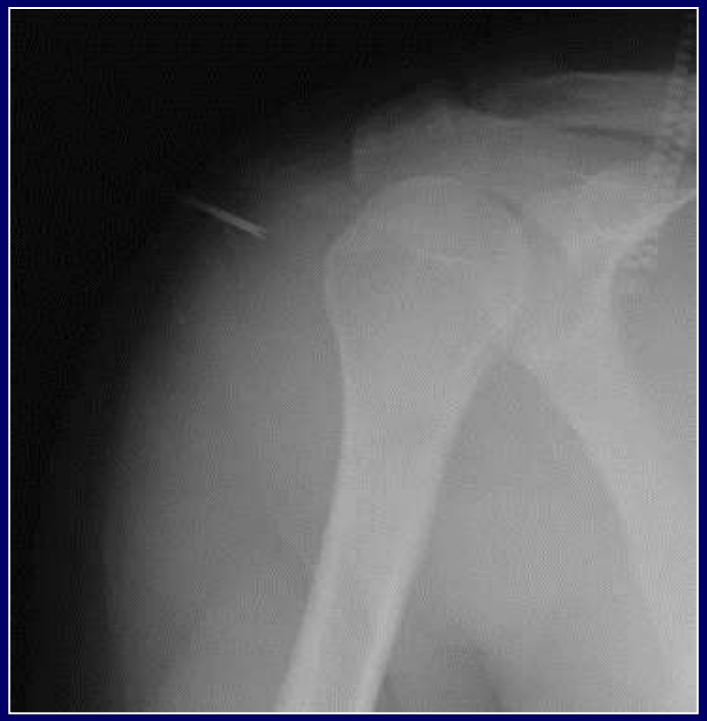
CASE STUDY # 3:

Axial CT shows both needles (blue hub) do not penetrate the bone cortex.



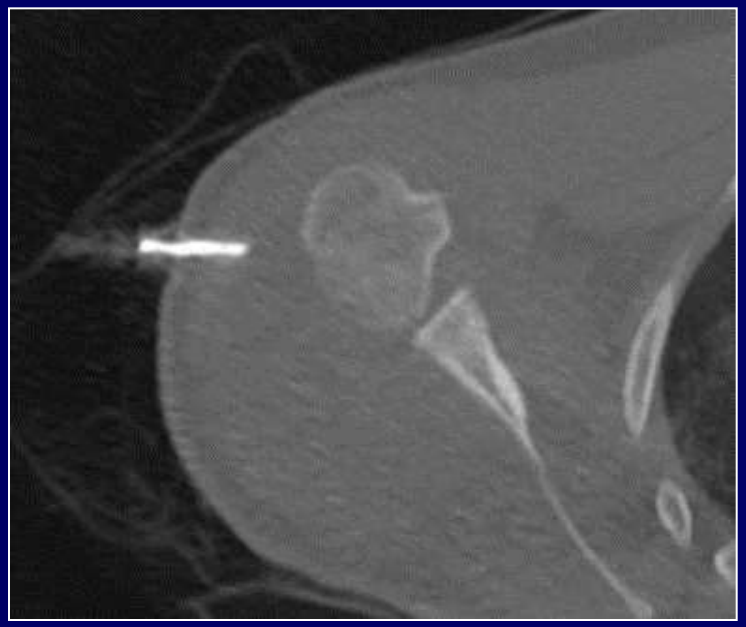
CASE STUDY # 4:

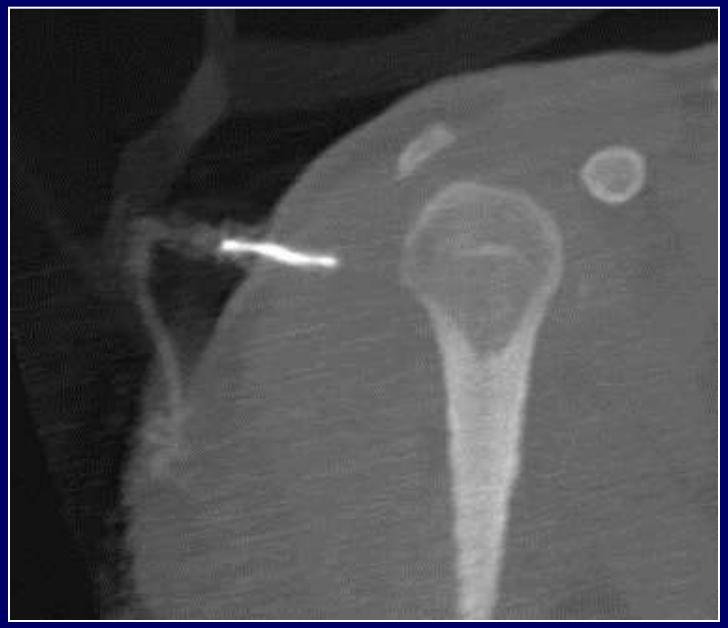
Attempt made to place an IO-IV in the proximal right humerus. Note that the plastic hub of the needle is blue.



CASE STUDY # 4:

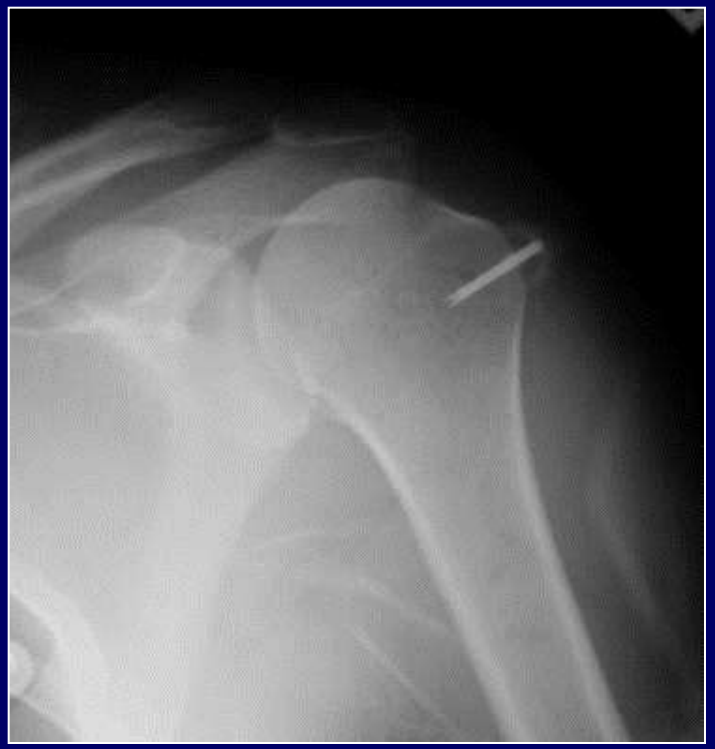
Axial and coronal CT shows the needle (blue hub) does not penetrate the bone cortex.





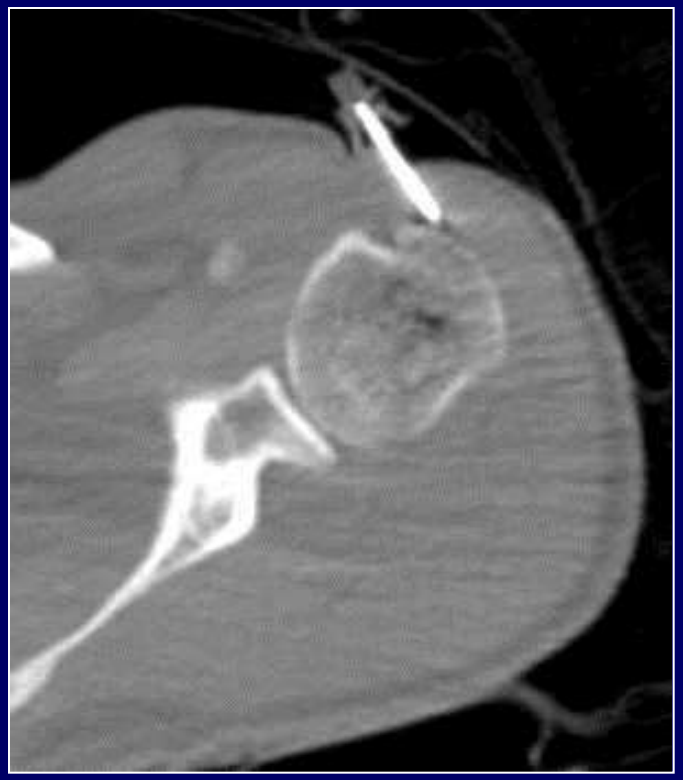
CASE STUDY # 5:

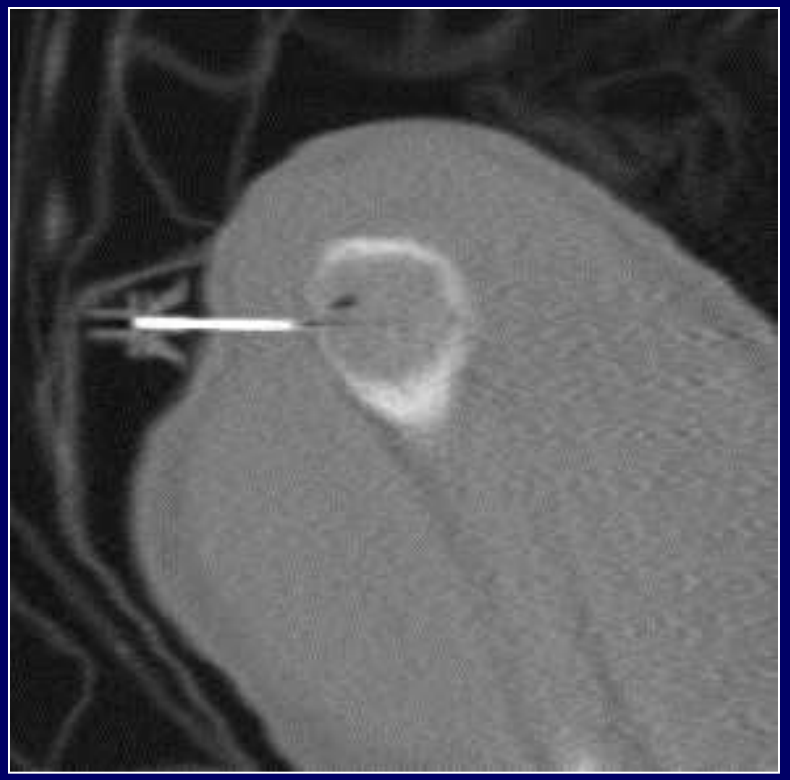
Attempt made to place an IO-IV in the proximal left humerus. Note that the plastic hub of the needle is blue.



CASE STUDY # 5:

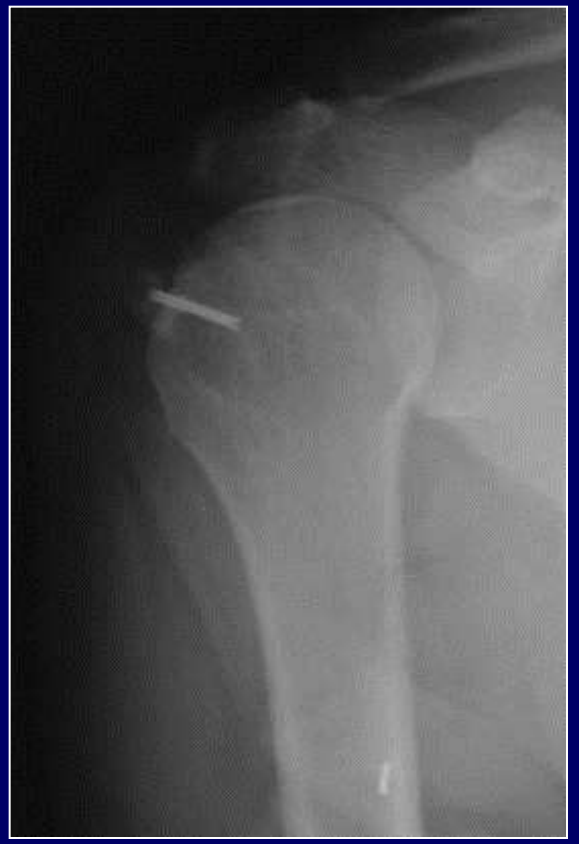
Axial and coronal CT shows the needle (blue hub) does not penetrate the bone cortex.





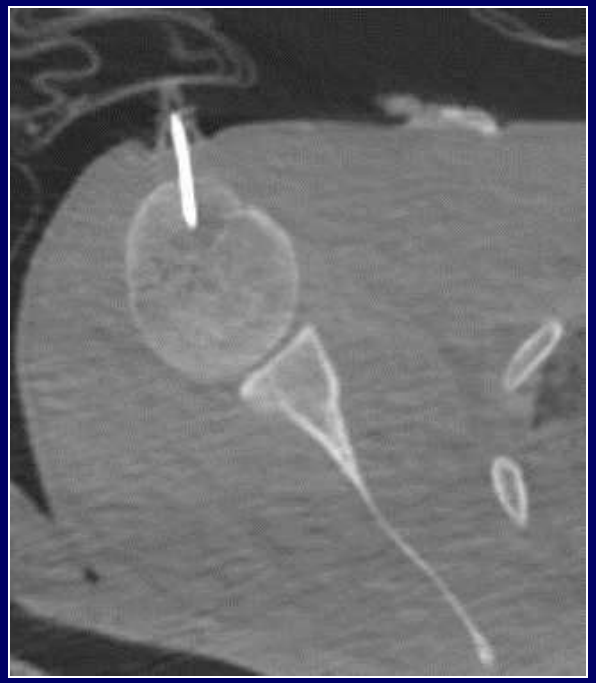
CASE STUDY # 6:

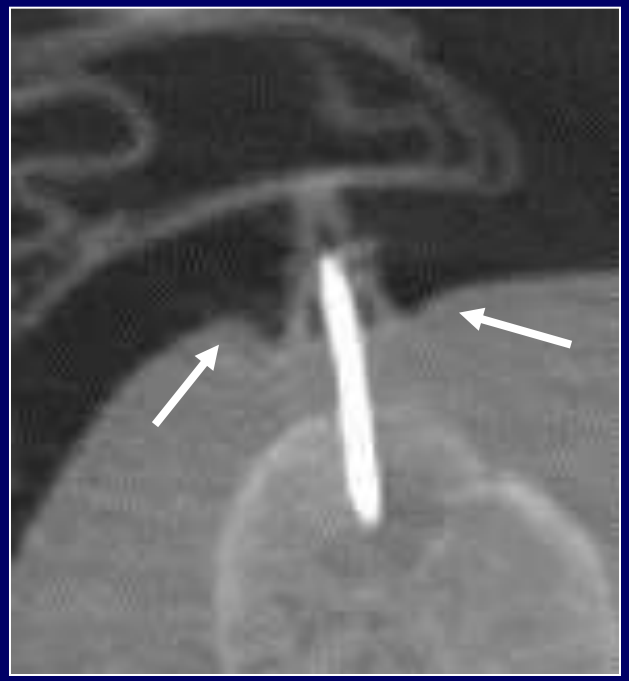
Two (2) attempts made to place an IO-IV in the proximal right humerus. Note that the plastic hub of the needle is blue.



CASE STUDY # 6:

Axial CT shows the second attempt needle (assumed) penetrates the bone cortex. Note the superficial soft tissue compression (arrows) needed for the blue hub needle to penetrate the bone cortex.





SUMMARY

Past experience suggests:

- the yellow hub needle for a humeral IO-IV
- the blue hub needle for a tibial IO-IV
- the green hub needle for a sternal IO-IV
- the pink hub needle for pediatric use

Exceptions are possible (see case 6) depending upon tissue thickness, approach, and availability but variations may reduce success rate (cases 3,4,5)

Pink hub needles should be reserved for pediatric use (cases 1,2)

DHA MEDLOG research reveals the following:

User feedback:

- Adult and pediatric IO-IV devices are being stored together; therefore, increasing the chance of using the wrong needle

- Possible lack of training and familiarity on various IO-IV devices, hub colors, and needle lengths

User feedback (continued)

- The color of EZ-IO® hub used for “training” is RED; this is extremely close to pediatric EZ-IO® hub color, which is PINK
- The RED and PINK hubs are hard to differentiate in varying or low light conditions
- Package label text size is not sufficient; the weight and IO-IV dimensions are hard to read in varying light conditions (e.g., too bright, low light condition, and when using NVGs)

User feedback (continued)

- Feedback from one of the caregivers in the field stated that they are having trouble obtaining EZ IO® 25mm (Blue hub) through their supply chains, forcing them to use non-standard needle lengths to obtain IO-IV placement

- “Providers who are forced to choose between too short or too long needles, not wanting to overshoot and coming up short.”

DHA MEDLOG research (continued)

- On 11 Feb 14, Trillamed (formerly Vidacare) received FDA clearance approval to change labeling of EZ-IO® 25mm needle set (Blue) from “40 kg or over” to “3 kg or over,” giving clinicians option to choose needle length based on patient’s weight and variability in each patient’s anatomy

- Trillamed cited performance data, clinical studies, and Vidacare’s experience with the EZ-IO® for the change in labeling.

  http://www.accessdata.fda.gov/cdrh_docs/pdf13/K132583.pdf

Ordering issues:

- Cataloging in the medical logistics systems all have the same description, regardless of IO-IV size; there is also inconsistency in needle length unit of measurement (i.e. *mm* vs. *cm*)

- Orders are being placed incorrectly by non-logistic or non-medical personnel

- Adult and pediatric IO-IV devices were purchased on a 3:1 ratio; average number of in-theater pediatric admissions for the last 15 months is 3 per month

Actions:

- DHA MEDLOG has updated medical logistics systems/databases to: (1) denote adult, large adult, or pediatric size in short description line, and (2) changed length to centimeters (cm) as standard unit for IO-IV lengths

- DHA MEDLOG has started notifying each Service and training schools regarding IO-IV use issues

DHA MEDLOG RECOMMENDATIONS

- Ensure Services have the correct EZ-IO® NSNs in their assemblages
- Unit equipment sets and medical logistics systems must be reviewed
- Ensure different types of IO-IV devices are labeled correctly and stored separately; this will prevent mix up and unintentional use of wrong device

DHA MEDLOG RECOMMENDATIONS

- Based on the recent FDA approval of labeling change for EZ-IO® 25mm needle set (Blue), providers must decide if they want to substitute Blue IO-IV for the pediatric IO (Pink)

- If so, ensure providers are trained in the use of adult EZ-IO® needle for pediatric patients

This material is intended for educational and training purposes. If portions are extracted, the following statement must be included:

"Source: Armed Forces Medical Examiner System and DHA Medical Logistics Division"

NOTES of CAUTION:

- The clinical circumstances and details surrounding emergency treatment in these cases is unknown
- This presentation makes no association between device placement and outcome of treatment
- This case series is drawn from cases with fatal injuries, which may skew data

For FT2F Comments / Questions / Requests:
Contact the Armed Forces Medical Examiner System (AFMES)

Contact Information:

Lt Col Edward L Mazuchowski, USAF, MC
Office of the Armed Forces Medical Examiner

edward.l.mazuchowski.mil@mail.mil
(302) 346-8648