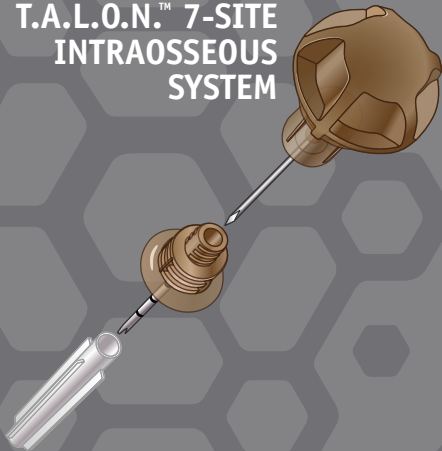




T.A.L.O.N.™ 7-SITE INTRAOSSEOUS SYSTEM



Instructions for Use

EZ-IO® by **vidacare®**
Intraosseous Vascular Access

Vidacare.com

DESCRIPTION:

T.A.L.O.N.™ (Tactically Advanced Lifesaving Intraosseous Needle) 7-Site Intraosseous System contains an EZ-IO® Manual Needle Set and a sternal locator. When the stylet is removed the catheter Luer Lock is exposed. The catheter is 15 gauge, 38.5 mm, made of 304 stainless steel and provided sterile, non-pyrogenic in a sealed kit. Device and Component(s) is/are not made with natural rubber latex.

EACH T.A.L.O.N.™ KIT CONTAINS:

- 1 EZ-IO® Manual Needle Set
- 1 Sternal Locator
- 1 NeedleVise®
- 1 EZ-Connect®
- 1 Instructions for Use
- 1 EZ-IO® Wristband

INDICATIONS FOR USE:

FOR INTRAOSSEOUS (IO) ACCESS IN ADULT PATIENTS WHEN RAPID FLUID OR PHARMACOLOGICAL RESUSCITATION IS REQUIRED IN EMERGENCIES:

- Sternum
- Proximal Humerus
- Proximal Tibia
- Distal Tibia

CONTRAINDICATIONS FOR USE:

- Fracture
- Excessive tissue (severe obesity) and/or absence of adequate anatomical landmarks
- Osteoporosis (sternal application only)
- Infection at the area of insertion
- Previous, significant orthopedic procedure at the site, prosthetic limb or joint
- IO at site in the past 48 hours

WARNINGS AND PRECAUTIONS:



WARNING: Sternal locator should not be used in the following sites:

- Proximal Humerus, Proximal Tibia or Distal Tibia

CAUTION: DO NOT USE the Manual Needle Set in the sternum WITHOUT the sternal locator.

CAUTION: Before administering vesicant, toxic, or highly-concentrated drugs, check the Manual Needle Set again for placement and patency.

CAUTION: Use aseptic technique.

CAUTION: (Sternal Site) Use with extreme caution in patients with suspected thoracic trauma such as air bag deployment to the chest or chest impacts with steering wheel.

CAUTION: 24 hour use only.

CAUTION: Single use only.

CAUTION: DO NOT recap Needle Sets or separated components.

Use biohazard and sharps disposal precautions.

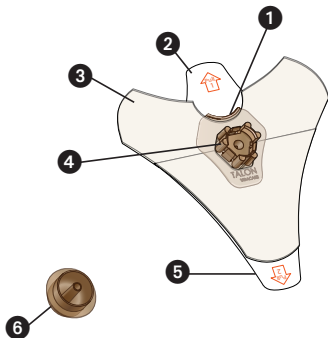
Re-use of contents may cause cross contamination, leading to patient risk and complication(s).

CAUTION: Check skin thickness before Manual Needle Set insertion on all patients (See Figure 20). Special caution must be exercised in use with patients with BMI greater than 30. Sternal Locator probes should rest firmly on the manubrial surface prior to Manual Needle Set insertion. Manual Needle Set cannot be used in the sternum if the probes do not seat on the bone.

CAUTION: Stylet and catheter are not MRI compatible.

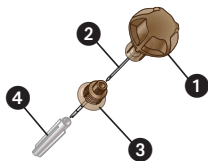
STORAGE: -18 C to 48 C (0°F to 120°F).

T.A.L.O.N.™ SYSTEM COMPONENTS



Sternal Locator:

- 1 Sternal Locator
- 2 Tab 1
- 3 Adhesive Tape
- 4 Locator Hub
- 5 Tab 2
- 6 Needle Cap



Manual Needle Set:

- 1 Manual Handle
- 2 Stylet
- 3 Catheter
- 4 Needle Cap

STERNAL INSERTION STEPS:

WARNING: The sternal locator MUST be used when placing the Manual Needle Set into the sternum.

1. **Take appropriate Body Substance Isolation (BSI) Precautions.**
2. **Use aseptic technique.**
3. **Locate insertion site.** (See Figures 1 and 2)
4. **Prepare insertion site.**
(See Figure 2 for proper locator orientation)
5. **Prepare infusion system.** Prior to attaching EZ-Connect® perform the following steps:
 - a. Open clamp.
 - b. Attach female adapter to syringe or IV tubing.
 - c. Prime EZ-Connect® with saline or 2% preservative free lidocaine and purge air.
6. **Remove sternal locator needle cap and pull tab 1.** (See Figure 3)

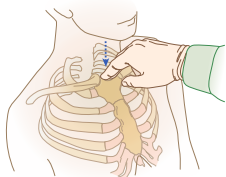


FIGURE 1

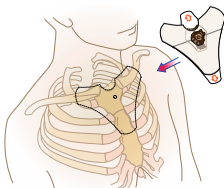


FIGURE 2

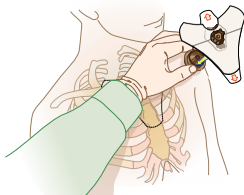


FIGURE 3

7. **Align curve in top of sternal locator with the suprasternal notch.**
(See Figure 4)
8. **Seat the depth probes of the sternal locator on the surface of the sternum by pressing down firmly with both hands.** (See Figure 5)
9. **Firmly press down adhesive tape.**
10. **Holding the sternal locator in place, pull tab 2 to expose the adhesive on the bottom half of the sternal locator.** (See Figure 6)
11. **Firmly press down remaining adhesive tape.**

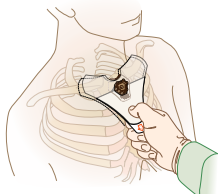


FIGURE 4

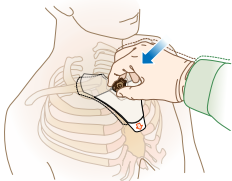


FIGURE 5

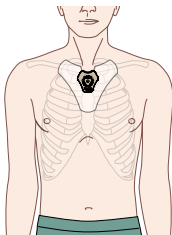


FIGURE 7

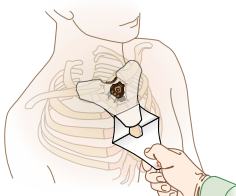


FIGURE 6

12. **Remove and discard Needle Set safety cap.** (See Figure 8)

IMPORTANT: Do not touch the Needle Set with your hand or fingers.

IMPORTANT: Control the patient's movement.

IMPORTANT: Ensure stylet is tightly screwed together with catheter prior to insertion.

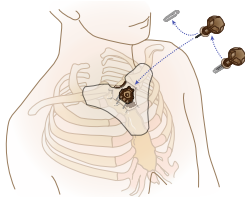


FIGURE 8

13. **Insert.**

a. Insert Needle Set tip into cone at the center of the Sternal Locator with needle at a 90-degree angle to the bone. (See Figures 9 and 10)

b. **Gently** insert Needle Set until it seats on bone.

c. Penetrate bone cortex by rotating clockwise while applying **gentle, steady downward pressure.** (10-15 lbs, 5-7 kgs)

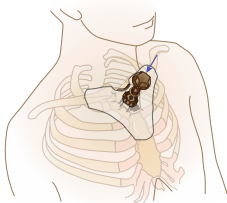


FIGURE 9

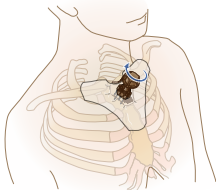


FIGURE 10

d. Stop insertion process upon entry into the medullary space and a click is felt or heard as the Needle Set hub locks into the Sternal Locator hub. (See Figures 10 and 11)

e. Do not rock or bend during Manual Needle Set insertion. **MAINTAIN 90-DEGREE ANGLE.**

14. **Remove stylet** and place into NeedleVise® for sharps containment. (See Figure 12)

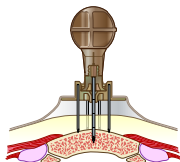


FIGURE 11

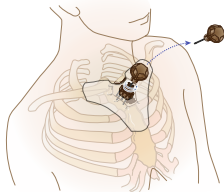


FIGURE 12

15. Attach primed EZ-Connect® and tighten.

- Attach male adapter to access device with a firm push and twist motion.
- Engage Luer Lock collar in order to prevent accidental disconnection. (See Figure 13)

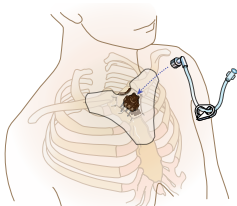


FIGURE 13

16. Flush the EZ-IO® catheter with 5-10 ml of Normal Saline. (See Figure 14)

IMPORTANT:

- Prior to flush consider the aspiration of a small amount of blood to confirm placement.
- For patients responsive to pain consider 2% lidocaine without preservatives or epinephrine (cardiac lidocaine) administered slowly IO prior to flush. Follow institutional policy/procedure.
- Medications intended to remain in the medullary space, such as a local anesthetic, must be administered over 2 minutes until the desired effect is achieved.

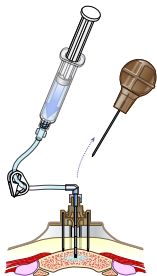


FIGURE 14

NO FLUSH = NO FLOW

Failure to appropriately flush the EZ-IO® catheter may result in limited or no flow.

REPEAT FLUSH AS NEEDED

Once EZ-IO® catheter has been flushed, administer fluids or medications using pressure as indicated. (See Figure 15)

NOTE: Frequently monitor the insertion site for extravasation.

NOTE: Hold T.A.L.O.N.™ System components firmly in place on patient during transfer to patient transport systems.

17. CATHETER REMOVAL:

- Peel back sternal locator adhesive tape from the chest.
- Attach Luer Lock syringe.
- Continuously rotate clockwise the syringe and catheter (not the sternal locator) while slowly and gently applying traction to the catheter. (See figure 16)

DO NOT ROCK OR BEND THE CATHETER DURING REMOVAL.

Once removed, immediately place catheter and sternal locator in appropriate sharps container.

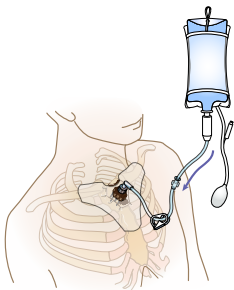


FIGURE 15

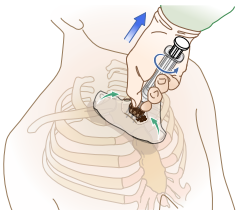
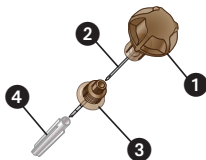


FIGURE 16

MANUAL USE:**DEVICE DESCRIPTION:**

EZ-IO® Manual Needle Sets contain a stylet and a catheter. When the stylet is removed the catheter Luer Lock is exposed. The catheter is 15 gauge, 38.5 mm, made of 304 stainless steel and provided sterile, non-pyrogenic in a sealed kit. Device and Component(s) is/are not made with natural rubber latex.

**Manual
Needle Set:**

- ❶ Manual Handle
- ❷ Stylet
- ❸ Catheter
- ❹ Needle Cap

INSERTION STEPS:

1. Take appropriate Body Substance Isolation (BSI) Precautions.
2. Use aseptic technique.
3. Locate insertion site. (See Figure 17)
4. Prepare insertion site.
(See Figure 18 – Tibial site shown for clarity)
5. Prepare infusion system.
6. Remove and discard the Needle Set safety cap.

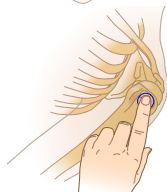
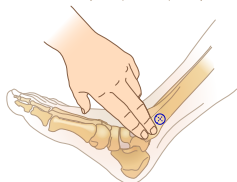
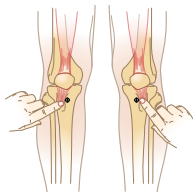


FIGURE 17

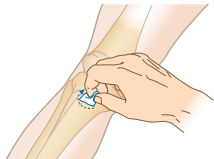


FIGURE 18

7. Insert. (See Figure 19)

IMPORTANT: Do not touch the catheter with your hand or fingers.

IMPORTANT: Control the patient's movement prior to and during Needle Set insertion.

IMPORTANT: Ensure stylet is tightly screwed together with catheter prior to insertion.



FIGURE 19

- a. Position manual driver at insertion site with Needle Set at a 90-degree angle to the skin. (See Figure 19)
Gently insert Needle Set until Needle Set tip touches bone.

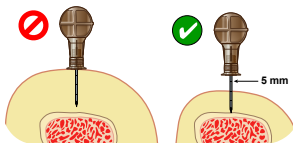


FIGURE 20

- b. Ensure at least 5 mm of catheter is visible. (See Figure 20)
- c. Penetrate bone cortex by rotating clockwise while applying **gentle, steady downward pressure**.
- d. Stop insertion process when a desired depth is obtained or catheter hub is flushed with the skin.
- e. Do not rock or bend during Needle Set insertion. **MAINTAIN 90° ANGLE.**

IMPORTANT: Use gentle-steady pressure – not excessive force. Allow catheter tip rotation and gentle downward pressure to provide penetrating action.

8. **Remove stylet** and place in NeedleVise® for sharps containment. (See Figure 21)

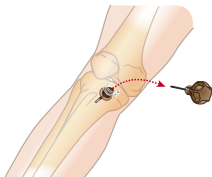


FIGURE 21

9. **Confirm catheter stability.** Catheter should be stabilized to prevent dislodgement.

10. **Attach primed EZ-Connect® extension set to Catheter Hub's Luer Lock.**

DO NOT ATTACH A SYRINGE DIRECTLY TO THE EZ-IO® CATHETER HUB'S LUER LOCK.

11. **Flush the EZ-IO® catheter with 5-10 ml of Normal Saline.** (See Figure 22)

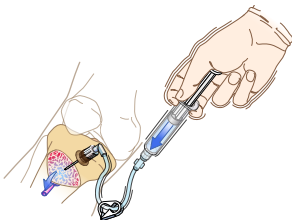


FIGURE 22

IMPORTANT: Prior to flush, aspirate a small amount of blood to confirm placement.

- a. **Consider IO lidocaine (preservation free) for conscious patients prior to flush.**
- b. **NO FLUSH = NO FLOW**
Failure to appropriately flush the IO catheter may result in limited or no flow. Repeat flush as needed.
- c. Once IO catheter has been flushed, administer fluids or medications as indicated.

NOTE: Frequently monitor the insertion site for extravasation.

NOTE: Hold T.A.L.O.N.™ System components firmly in place on patient during transfer to patient transport systems.

12. Apply dressing.

13. Remove catheter from patient.

Gently twist clockwise while slowly applying traction to catheter.

DO NOT ROCK OR BEND THE CATHETER DURING THIS PROCEDURE.

(See Figure 23)

Once removed, immediately place catheter in appropriate sharps container.

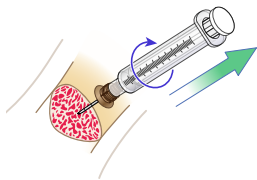


FIGURE 23

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

Education and training materials available at Vidacare.com.

NOTES:

Vidacare.com

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EC REP

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