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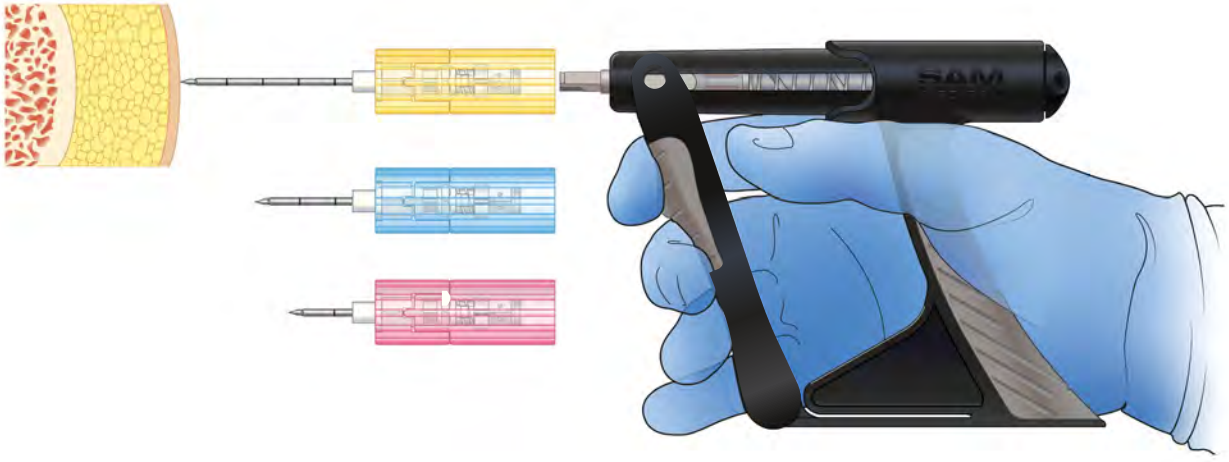
# SAM® IO Intraosseous Access System | Instructions for Use

# INSTRUCTIONS FOR USE



# INDICATIONS:

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

# CONTRAINDICATIONS:

1. Fracture in targeted bone.
2. Previous, significant orthopedic procedure at site selected for insertion.
3. Intraosseous catheter placement in targeted bone within past 48 hours.
4. Infection at site selected for insertion.
5. Excessive tissue or absence of anatomic landmarks.

# PRECAUTIONS, WARNINGS AND ADVISORY FOR SAM IO™ INTRAOSSEOUS ACCESS SYSTEM

## ⚠ CAUTIONS:

- Stylet and catheter are NOT MRI compatible.
- Assess skin, adipose and muscle thickness before insertion.
- Use aseptic technique.
- Needle assembly is single use only.
- Do not recap needle assembly or reconnect separated components.
- Re-use of supplied sterile contents may cause illness or injury.
- Minimize or restrict patient movement during insertion.
- Care should be taken during insertion and treatment when used for patients who have bone diseases that increase likelihood of fracture, extravasation or dislodgement.
- Use biohazard and sharps disposal precautions.
- Monitor insertion site frequently for extravasation.
- Do not leave catheter inserted for more than 24 hours.
- Additional consideration to skeletal maturity should be used when considering use on neonates/newborns weighing less than 3 kg.
- Not for Sternal use.

# ADVISORY:

SAM IO™ Intraosseous Access System and IFU familiarization, intraosseous access training, as well as adherence to established evidence based guidelines, are required for use of this product. Failure to utilize this device in a manner consistent with approved IFU, IO training, and within clinical best practice guidelines, may result in serious illness or injury.

These instructions for use pertain to adults and the following pediatric subgroups:

- Birth to 1 month of age – Neonate (Newborn)
- >1 month to 2 years of age – Infant
- >2 to 12 years of age – Child
- >11 to 13 years of age – Pre-Adolescent
- >12 to 21 years of age – Adolescent

Some insertion sites and needle lengths are generally recommended for specific adult/pediatric subgroups. Please read carefully the recommendations presented in table 1 below.

**NOTE:** When determining the anatomical site and needle length for intraosseous access, patient age and physiology should be considered per protocol or standard, and on a case by case basis based on clinical judgement. Additional consideration to skeletal maturity should be used when considering use on neonates/newborns weighing less than 3 kg including:

- Low birth weight – Neonate (newborn) less than 2.5 kg
- Very low birth weight – Neonate (newborn) less than 1.5 kg

*(table 1)*

| | ADULT | PEDIATRIC |
|---|---|---|
| **15 mm** | For **adult patients** with non-existent to limited overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia** | For **pediatric patients** with non-existent to limited overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia**<br>**d. Distal Femur** |
| **25 mm** | For **adult patients** with minimal to moderate overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia** | For **pediatric patients** with minimal to moderate overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia**<br>**d. Distal Femur** |
| **45 mm** | For **adult patients** with moderate to excessive overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia** | For **pediatric patients** with moderate to excessive overlying adipose tissue. Recommended insertion sites:<br>**a. Proximal Humerus**<br>**b. Proximal Tibia**<br>**c. Distal Tibia**<br>**d. Distal Femur** |

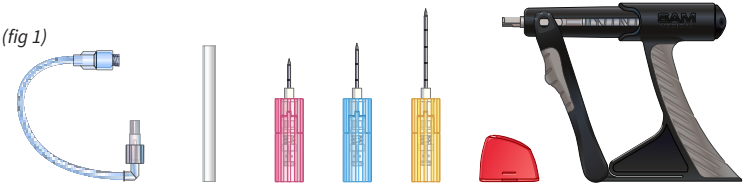
## ATTENTION:

U.S. Federal and international laws restrict this device for sale to, or under the direct order of, a licensed physician.

## DEVICE DESCRIPTION:

SAM IO™ is a manually operated intraosseous access system (fig 1). Catheter placement is achieved by continuously actuating (repeatedly compressing) driver's trigger assembly while gently guiding needle assembly into position. Repeated, full trigger actuation creates rotational spin of needle assembly which, when combined with gentle downward pressure, results in controlled IO placement. Once needle assembly is properly positioned, stylet is removed to expose standard Luer-lock for extension set connection. With extension set connected, aspiration verification, flushing and selected treatment(s) may commence.

*(fig 1)*




## INSERTION SITES: (fig 2 – 8)

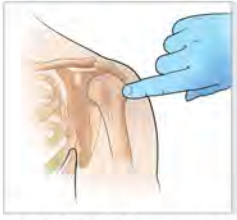
For pediatric patients, general recommendations for needle set length and insertion sites selection include the following:

- 15 mm: Neonates and small infants proximal and distal tibia
- 25 mm: Neonates and small infants in distal femur, proximal and distal tibia

**NOTE:** Depth marking verification must still be done prior to insertion.

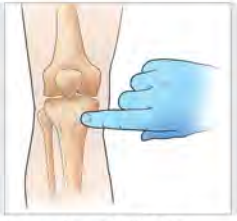
# INSERTION SITES CONT.

## ADULT (fig 2 – 4)



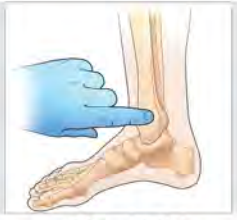
Proximal Humerus

*(fig 2)*



Proximal Tibia

*(fig 3)*



Distal Tibia

*(fig 4)*

Distal Femur - For pediatric use only.

## PEDIATRIC (fig 5 – 8)

**Proximal Humerus**

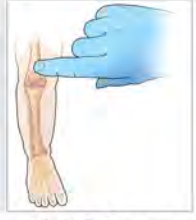
*(fig 5)*

Proximal Tibia

*(fig 6)*

Distal Tibia

*(fig 7)*



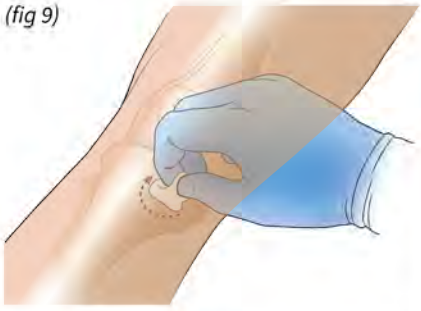
Distal Femur

*(fig 8)*

# INSERTION STEPS:

## 1

*(fig 9)*



Clean insertion site per institutional protocol or policy *(fig 9)*.

## 2

**PREPARE SUPPLIES:**

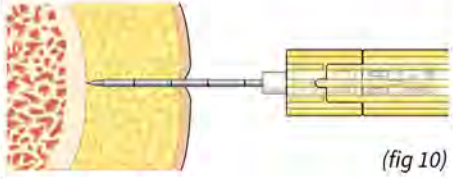
- Prime infusion set.
- Attach needle assembly to driver.
- Remove safety cap from needle assembly.

**IMPORTANT:** Do not touch uncapped, sterile components of needle assembly.

**IMPORTANT:** Control patient movement prior to and during procedure.

## 3

Insert needle assembly through skin and adipose tissue. Needle assembly tip should come to rest against targeted periosteum / bone *(fig 10)*.



*(fig 10)*

# 4

Ensure that ≥ 5 mm of catheter (at least first black line on proximal catheter) is visible above the skin (fig 10).

**IMPORTANT:** Most accurate determinant of needle assembly length related to safe intraosseous access are black depth indicators on catheter.

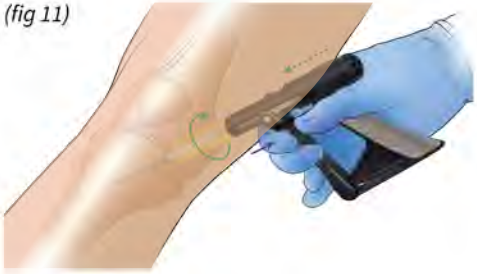
- Depth indicators function as measuring guide to determine amount of soft tissue overlying targeted bone.
- Depth verification must be accomplished prior to insertion attempt in order to determine if needle assembly length is adequate to reach medullary space.
  - **15 mm** needle assembly suggested for patients with non-existent to limited overlying adipose tissue (general weight range between 3-39 kg).
  - **25 mm** needle assembly suggested for patients with minimal to moderate overlying adipose tissue (general weight range ≥3 kg).
  - **45 mm** needle assembly suggested for patients with moderate to excessive overlying adipose tissue (general weight range ≥40 kg).

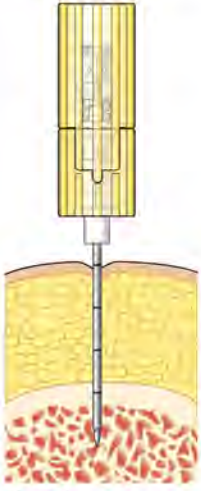
**NOTE:** Needle set selection starts with the general weight ranges but ultimately, the true measurement can be found by use of the black line, and post-insertion placement confirmation steps to further validate correct insertion depth.

# 5

Continuously actuate (repeatedly compress) driver's trigger assembly, while applying gentle, steady downward insertion pressure to achieve controlled entry *(fig 11 & 12)*.

*(fig 11)*





*(fig 12)*

**IMPORTANT: DO NOT USE EXCESSIVE FORCE.** Use minimal (gentle) steady downward insertion pressure. Allow needle assembly tip rotation to penetrate compact bone. The mechanical rotation of the needle by handle actuation and the cutting edge of the needle should be the PRIMARY mechanisms to penetrate bone, NOT the force of downward pressure. Begin with little to no downward pressure, and gradually increase light pressure until advancement of the needle by handle actuation is achieved. Each patient may require a different amount of force to be applied. (fig 12).

## 5 Cont.

**NOTE:** If you cannot actuate (compress) trigger, or device fails to rotate and needle assembly will not penetrate bone, you may be applying excessive downward pressure on system.

**NOTE:** In unlikely event of driver failure, grasp needle assembly by hub and disconnect from driver. While holding needle assembly hub as illustrated, offer gentle downward pressure, while alternately rotating (twisting back and forth) to advance tip into medullary space. Do **NOT** use excessive force, and do **NOT** rock or bend needle set during insertion. *(fig 13)*.

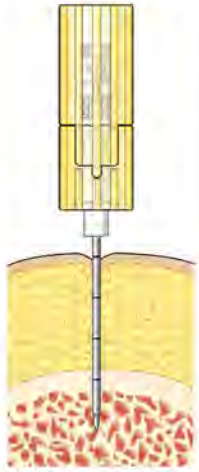
*(fig 13)*

## 6

Advance needle assembly into desired position.

- For adult and pediatric insertions: Discontinue trigger actuation when subtle "give" or "pop" is appreciated, indicating needle assembly entry into medullary space *(fig 12)*.

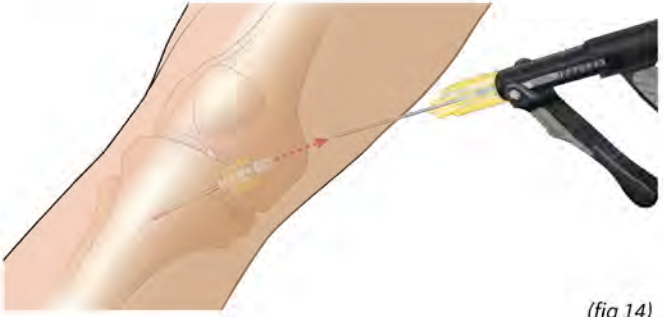
  **NOTE:** It is rarely necessary, nor advised, to have catheter hub flush against skin.



*(fig 12)*

## 7

Remove stylet by stabilizing needle assembly hub while retracting (lifting off) and disconnecting driver. Stylet will remain attached to driver *(fig 14)*.



*(fig 14)*

## 8

Disconnect stylet from driver. Place stylet into provided NeedleVISE® or appropriate sharps containment device *(fig 15)*.

*(fig 15)*

## 8 Cont.

**NOTE:** Place provided NeedleVISE® on flat stable surface. Immediately following insertion of needle set and release of stylet, while still holding stylet hub in one hand, firmly insert stylet tip directly down into opening of NeedleVISE® until it stops. Ensure HANDS AND FINGERS ARE AWAY FROM NeedleVISE®.

DO NOT HOLD NeedleVISE® WITH FREE HAND WHILE INSERTING STYLET.

ALWAYS USE ONE-HANDED TECHNIQUE WHEN INSERTING SHARP INTO NeedleVISE®.

Always safely dispose of opened sharps with provided NeedleVISE®.

## 9

The SAM IO Stabilizer is recommended for all insertions. Please reference the SAM IO Stabilizer Instructions for Use.

## 10

**OPTIONAL:** Obtain blood samples for laboratory analysis.

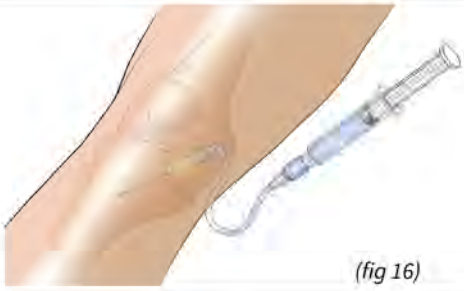
**NOTE:** Syringe may be directly attached to SAM IO™ catheter hub for aspiration of blood and subsequent laboratory analysis (ensure catheter is manually stabilized during aspiration).

## 11

Attach primed extension set to catheter hub, firmly secure by twisting clockwise *(fig 16)*.

**NOTE:**

- Do not use instruments to tighten connections.
- To prevent valve damage, do not use needle or blunt cannula to access extension set port.
- Non-standard syringe or connector can damage extension set port.
- Extension set port should be cleansed according to institutional protocol and standard.



*(fig 16)*

## 12

**OPTIONAL:** For patients responsive to pain, consider administration of preservative and epinephrine free 2% lidocaine (intravenous lidocaine), follow institutional protocol and standard.

- Anesthetic intended for medullary space should be administered slowly until desired effect is achieved.

## 13

Confirmation (and reconfirmation) of catheter placement should include one or more recommended methods:

- Identified blood at stylet tip.
- Noted stability of catheter in bone.
- Noted ability to aspirate blood from catheter.
- Noted ability to flush catheter without extravasation.
- Appreciation of adequate flow rate.
- Noted patient response to medication or fluid.

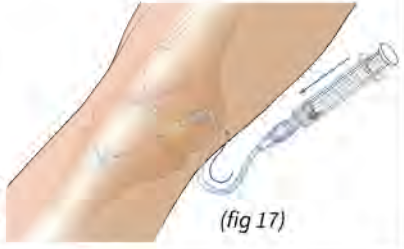
## 14

Flush SAM IO™ with normal saline as directed by protocol or standard. Repeat flush as needed *(fig 17)*.

- Prior to flush, aspirate IO catheter for visual confirmation of blood.
- Failure to appropriately flush SAM IO™ catheter may result in limited or no flow.
- Once SAM IO™ catheter has been flushed, administer fluids and medications per protocol or standard.

**CAUTION:**

- Monitor insertion site frequently for extravasation.
- Do not leave catheter inserted for more than 24 hours.

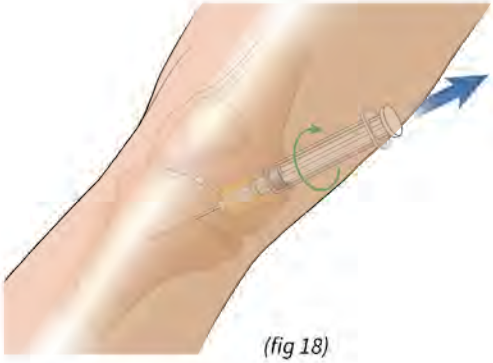


*(fig 17)*

# 15

To remove SAM IO™ catheter from patient *(fig 18)*:

- Remove extension set.
- Attach a sterile 10 ml Luer-lock syringe to hub of catheter.
- While continuously rotating catheter clockwise (to the right), slowly apply gentle traction.
- Maintain axial alignment during withdrawal.
- Do not rock or bend catheter during removal process.
- Once catheter removed, immediately place syringe and catheter in appropriate sharps container.
- Dress site per protocol and standard.



*(fig 18)*

# SYMBOL GLOSSARY:

| | |
|---|---|
| Indicates a medical device that should not be used if the package has been damaged or opened. |  |
| Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure. |  |
| Indicates a medical device that has been sterilized using ethylene oxide. |   |
| For prescription use only. |   |
| Indicates the date after which the medical device is not to be used. |  |
| Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC. |  |
| Not for Sternal use. |   |

| | |
|---|---|
| Indicates a medical device that needs protection from light sources. |  |
| Indicates a medical device that needs to be protected from moisture. |  |
| Indicates the need for the user to consult the instructions for use. |  |
| Indicates a medical device that is not to be resterilized. |   |
| Indicates the manufacturer's batch code so that the batch or lot can be identified. |   |
| Indicates the manufacturer's catalog number so that the medical device can be identified. |   |

# ENGINEERED FOR SURVIVAL

REF IO705-1P-EN - 15 mm/ 1 Pack

REF IO705-5P-EN - 15 mm/ 5 Pack

REF IO706-1P-EN - 25 mm/ 1 Pack

REF IO706-5P-EN - 25 mm/ 5 Pack

REF IO707-1P-EN - 45 mm/ 1 Pack

REF IO707-5P-EN - 45 mm/ 5 Pack

SAM04032 A

GET TRAINED:
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SAM® MEDICAL

IO-Needle-IFU-1