SAM IO®

INTRAOSSEOUS ACCESS SYSTEM

EN INSTRUCTIONS FOR USE

INDICATIONS:

The SAM IO Intraosseous Access System provides intraosseous access in the proximal tibia ***(fig 3, 6)***, distal tibia ***(fig 4, 7)*** and humeral head (proximal humerus) ***(fig 2, 5)*** of adults and pediatric patients, and the distal femur ***(fig 8)*** in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

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 these instructions.

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

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 assembly 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

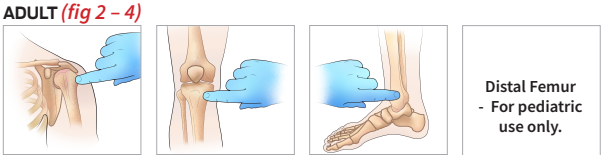
NOTE: Depth marking verification must still be done prior to insertion.

INSERTION SITES AND NEEDLE LENGTH RECOMMENDATIONS

(ADULT fig 2-4, PEDIATRIC fig 5-8)

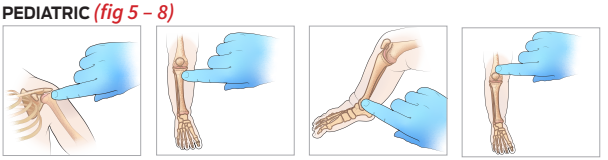
- 15mm - For adult and pediatric patients with non-existent to limited overlaying adipose tissue.
- 25mm - For adult and pediatric patients with minimal to moderate overlaying adipose tissue.
- 45mm - For adult and pediatric patients with moderate to excessive overlaying adipose tissue.

ADULT *(fig 2 – 4)*



Proximal Humerus *(fig 2)* | Proximal Tibia *(fig 3)* | Distal Tibia *(fig 4)*

PEDIATRIC *(fig 5 – 8)*

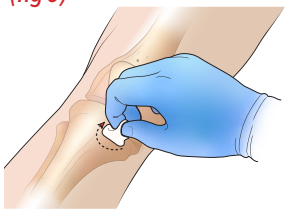


Proximal Humerus *(fig 5)* | Proximal Tibia *(fig 6)* | Distal Tibia *(fig 7)* | Distal Femur *(fig 8)*

INSERTION STEPS:

STEP 1

(fig 9)



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

STEP 2

PREPARE SUPPLIES:

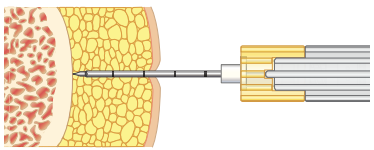
- Prime infusion set.
- Attach needle assembly to driver.
- Remove safety cap from needle assembly.

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

IMPORTANT: Control patient movement prior to and during procedure.

STEP 3

(fig 10)



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

STEP 4

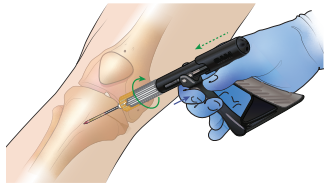
Ensure that ≥ 5 mm of catheter (at least first black line on proximal catheter) is visible above the skin *(fig 10)*.

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

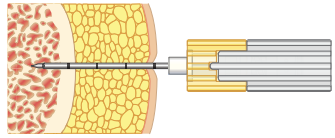
- Depth indicators function as measuring guide to determine amount of soft tissue overlying targeted bone.
- Depth verification must be accomplished prior to insertion attempt in order to determine if needle assembly length is adequate to reach medullary space.
- **15 mm** needle assembly suggested for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

NOTE: Needle assembly 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.

STEP 5



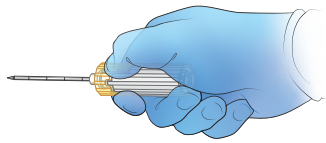
(fig 11)



(fig 12)

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

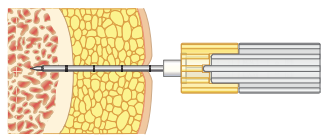


(fig 13)

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: If driver is unavailable, a manual insertion technique can be applied. While holding needle assembly hub as illustrated *(fig 13)*, 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 assembly during insertion.

STEP 6



(fig 12)

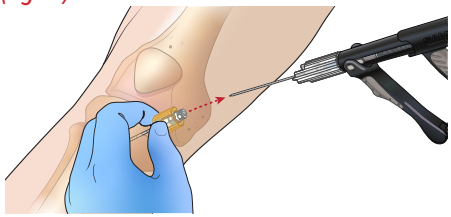
Advance needle assembly into desired position.

- 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.

STEP 7

(fig 14)



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

STEP 8

(fig 15)

While holding the driver, guide the stylet into provided NeedleVISE® or appropriate sharps containment device and disconnect stylet from driver ***(fig 15)***.

NOTE: Place provided NeedleVISE on flat stable surface. Immediately following insertion of needle assembly and release of stylet from catheter, while holding driver in hand with stylet still attached, firmly guide 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.

STEP 9

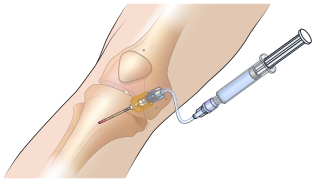
The SAM IO® Stabilizer is recommended for all insertions. Please reference the SAM IO Stabilizer Instructions for Use.

STEP 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).

STEP 11

(fig 16)



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

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.

STEP 12

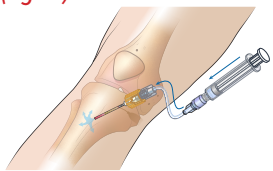
OPTIONAL: For patients responsive to pain, consider administration of preservative and epinephrine free 2% lidocaine (intravenous lidocaine), follow institutional protocol and standard.
- Anesthetic intended for medullary space should be administered slowly until desired effect is achieved.

STEP 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.
- Appreciation of adequate flow rate.
- Noted ability to flush catheter without extravasation.
- Noted patient response to medication or fluid.

STEP 14

(fig 17)



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

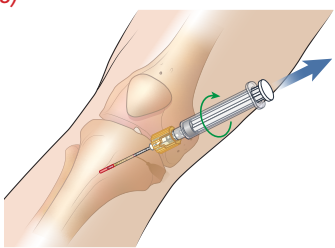
- Prior to flush, aspirate IO catheter for visual confirmation of blood.
- Failure to appropriately flush SAM IO catheter may result in limited or no flow.
- Once SAM IO catheter has been flushed, administer fluids and medications per protocol or standard.

CAUTION:

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

STEP 15

(fig 18)



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 is removed, immediately place syringe and catheter in appropriate sharps container.
- Dress site per protocol and standard.

NOTICE: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the regulatory authority/competent authority of the Member State region in which the user and/or patient is established.

SYMBOL GLOSSARY:

Symbol	Title (Reference)	Description
	Manufacturer (5.1.1[1])	Indicates the medical device manufacturer.
EC REP	Authorized representative in the European Community (5.1.2[1])	Indicates the authorized representative in the European Community/ European Union.
	Date of Manufacture (5.1.3[1])	Indicates the date when the medical device was manufactured.
	Use-by date (5.1.4[1])	Indicates the date after which the medical device is not to be used.
LOT	Batch Code (5.1.5[1])	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	Catalogue Number (5.1.6[1])	Indicates the manufacturer's catalog number so that the medical device can be identified.
	Importer (5.1.8[1])	Indicates the entity importing the medical device into the locale.
USA	Country of Manufacture (5.1.11[1])	To identify the country of manufacture of products.
STERILE EO	Sterilized using ethylene oxide (5.2.3[1])	Indicates a medical device that has been sterilized using ethylene oxide.
	Do not resterilize (5.2.6[1])	Indicates a medical device that is not to be resterilized.
	Do not use if package is damaged and consult instructions for use (5.2.8[1])	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	Single sterile barrier system (5.2.11[1])	Indicates a single sterile barrier system.
	Single sterile barrier system with protective packaging outside (5.2.14[1])	Indicates a single sterile barrier system with protective packaging outside.
	Keep away from sunlight (5.3.2[1])	Indicates a medical device that needs protection from light sources.
	Keep dry (5.3.4[1])	Indicates a medical device that needs to be protected from moisture.
2	Do not re-use (5.4.2[1])	Indicates a medical device that is intended for one single use only.
eIFU	Consult instructions for use or consult electronic instructions for use (5.4.3[1])	Indicates the need for the user to consult the instructions for use.
MD	Medical Device (5.7.7[1])	Indicates the item is a medical device.
UDI	Unique Device Identifier (5.7.10[1])	Indicates a carrier that contains unique device identifier information.
CE	CE Marking Regulation (EU) 2017/745 Article 20	Signifies European technical conformity.
Rx only	Prescription Only 21 CFR 801.109	Caution: Federal law restricts this device to sale by or on the order of a physician.
CH REP	Swiss Authorized Representative (Section 3[2])	Indicates the authorized representative in Switzerland.
x30	Package Quantity (No Applicable Reference)	Indicates a quantity of 30 single packs.
x6	Package Quantity (No Applicable Reference)	Indicates a quantity of 6 five packs.
Not For Sternal Use	Not For Sternal Use (No Applicable Reference)	Indicates device is not to be used on the sternum.
≥	Greater than or equal to (No Applicable Reference)	Greater than or equal to.

[1] ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
[2] Swissmedic, Obligations Economic Operators CH, VM-ID: MU600_00_016e/V4.0/mea/pmi/06.04.2023

EC REP
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REF **IO707W-1P** REF **IO707W-5P**

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