

A photograph showing two paramedics in blue uniforms with "OREGON PARAMEDIC" patches performing a medical procedure on a patient lying on a floor. One paramedic is kneeling and using a device on the patient's leg, while the other stands nearby. A woman with white hair is also kneeling, observing. Medical equipment, including a SAM IO Needle Set box and a SAM IO device, is visible in the foreground. The scene is dimly lit, suggesting an indoor setting at night.

SAM IO TRAINING

SAM
MEDICAL

SAM IO[®]

Intraosseous Access System

ADVISORY: Familiarization with SAM IO® access system, SAM IO® Instructions For Use, SAM IO® training materials, and adherence to established evidence-based guidelines are required for use of this product.

WARNING: Failure to utilize SAM IO® in a manner consistent with approved instructions for use, IO training materials, and within clinical best practice guidelines may result in serious illness, injury, or death.

ATTENTION: U.S. Federal law restrict this device for sale to, or under the direct order of, a licensed physician.

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PRECAUTIONS, WARNINGS & ADVISORIES

- Stylet and catheter (needle assembly) are NOT MRI compatible.
- Assess skin, adipose, and muscle thickness before SAM IO® 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.

TRAINING OBJECTIVES

At the conclusion of this didactic and recommended hands-on training session, you should be able to:

1. Identify SAM IO® components and functions.
2. List indications and contraindications for SAM IO® access.
3. Identify landmarks for SAM IO® access.
4. List steps for proper SAM IO® access.
5. Describe indicators of successful SAM IO® placement.
6. Demonstrate method for SAM IO® removal.

OBJECTIVE 1:

Identify SAM IO[®] components and functions.



NeedleWISE[®]



Extension Tube



Sheath



Stabilizer



15 mm Needle



25 mm Needle



45 mm Needle



Driver

OBJECTIVE 1:

Identify SAM IO[®] components and functions.



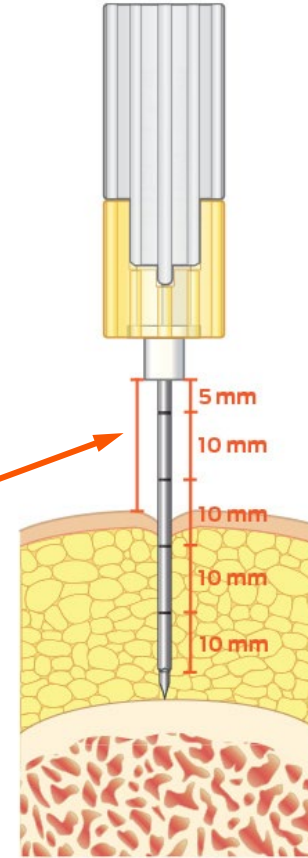
Remove SAM IO[®] Driver from box.

OBJECTIVE 1:

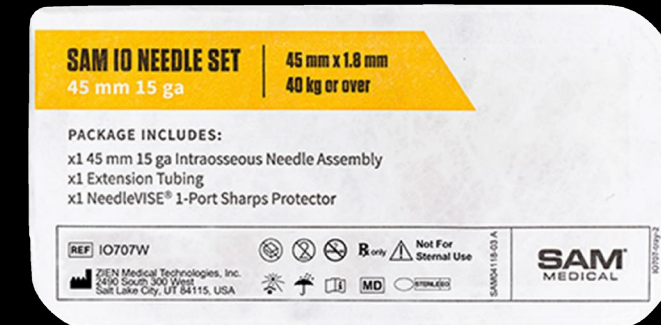
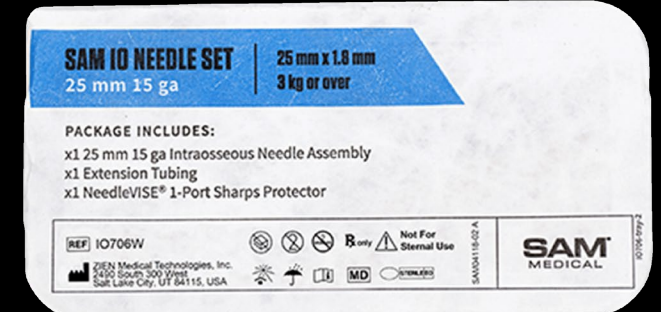
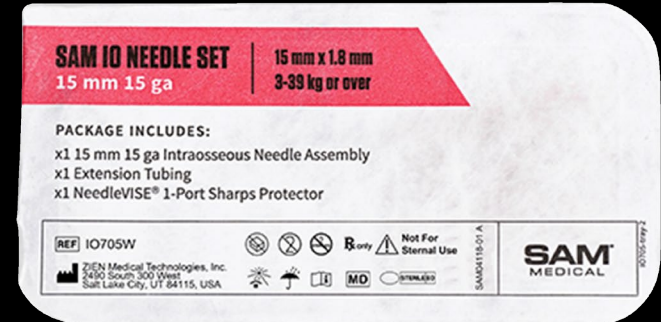
Identify SAM IO[®] components and functions.

Select appropriate SAM IO[®] needle assembly based on patient presentation.

Ensure ≥ 5 mm of needle assembly visible above skin (with assembly touching periosteum) before attempting SAM IO[®] insertion.



(Yellow) 45 mm needle assembly was selected for this illustration.



OBJECTIVE 1:

Identify SAM IO[®] components and functions.

Open an appropriately-sized needle assembly package and remove sterile contents as needed.



45 mm needle assembly selected
for this training program.

OBJECTIVE 2:

List Indications and Contraindications for the SAM IO®.

INDICATION FOR USE:

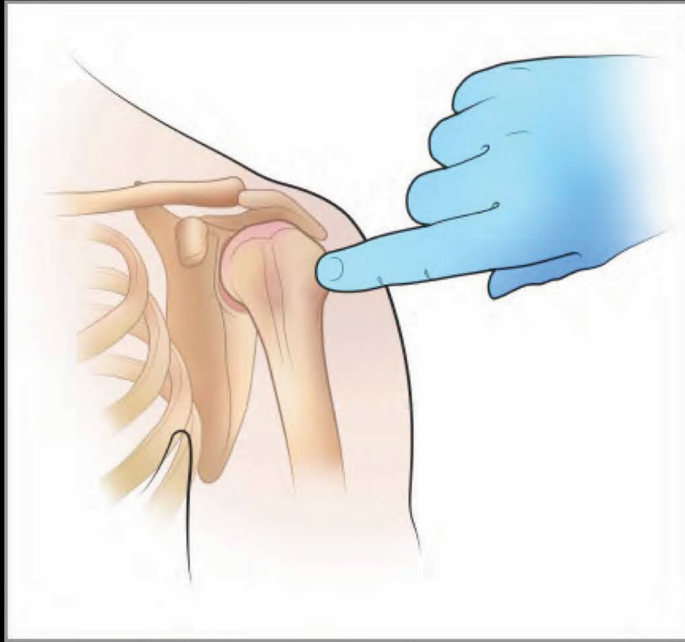
- The SAM IO® Intraosseous Access System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adults and pediatric patients, and the distal femur in pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent,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

CONTRAINDICATIONS:

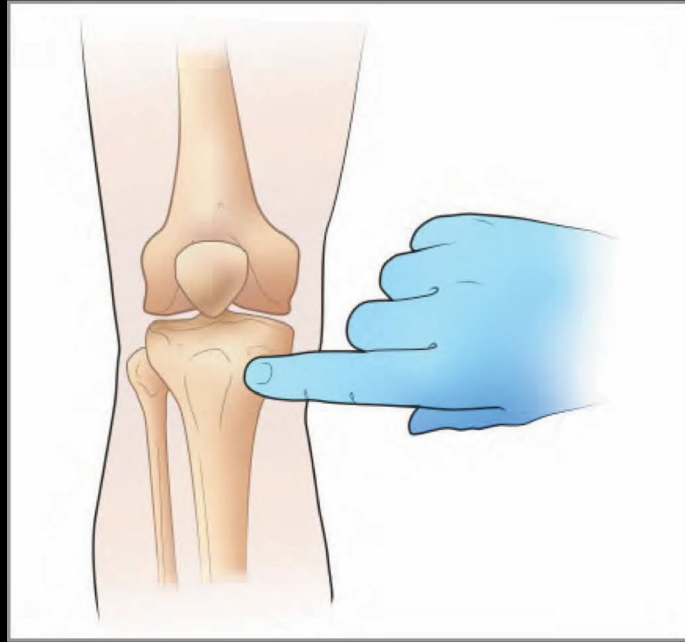
- Fracture in targeted bone.
- Previous, significant orthopedic procedure at site selected for insertion.
- Intraosseous catheter placement in targeted bone within past 48 hours.
- Infection at site selected for insertion.
- Excessive tissue or absence of anatomic landmarks.

OBJECTIVE 3:

Identify landmarks for SAM IO® access: ADULT



Proximal Humerus



Proximal Tibia



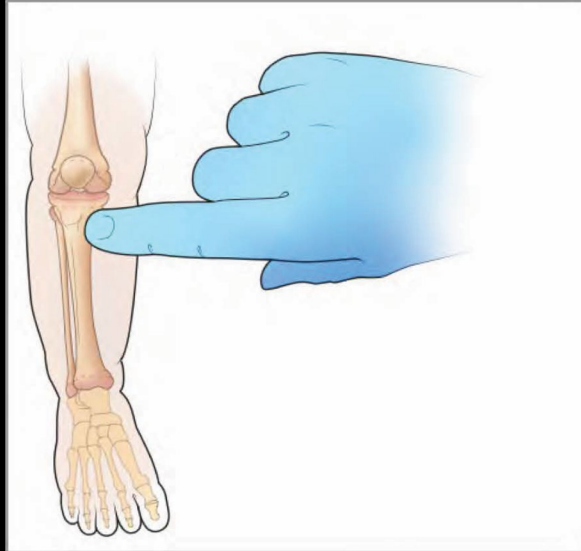
Distal Tibia

OBJECTIVE 3:

Identify landmarks for SAM IO[®] access: PEDIATRIC



Proximal
Humerus



Proximal
Tibia



Distal
Tibia



Distal
Femur

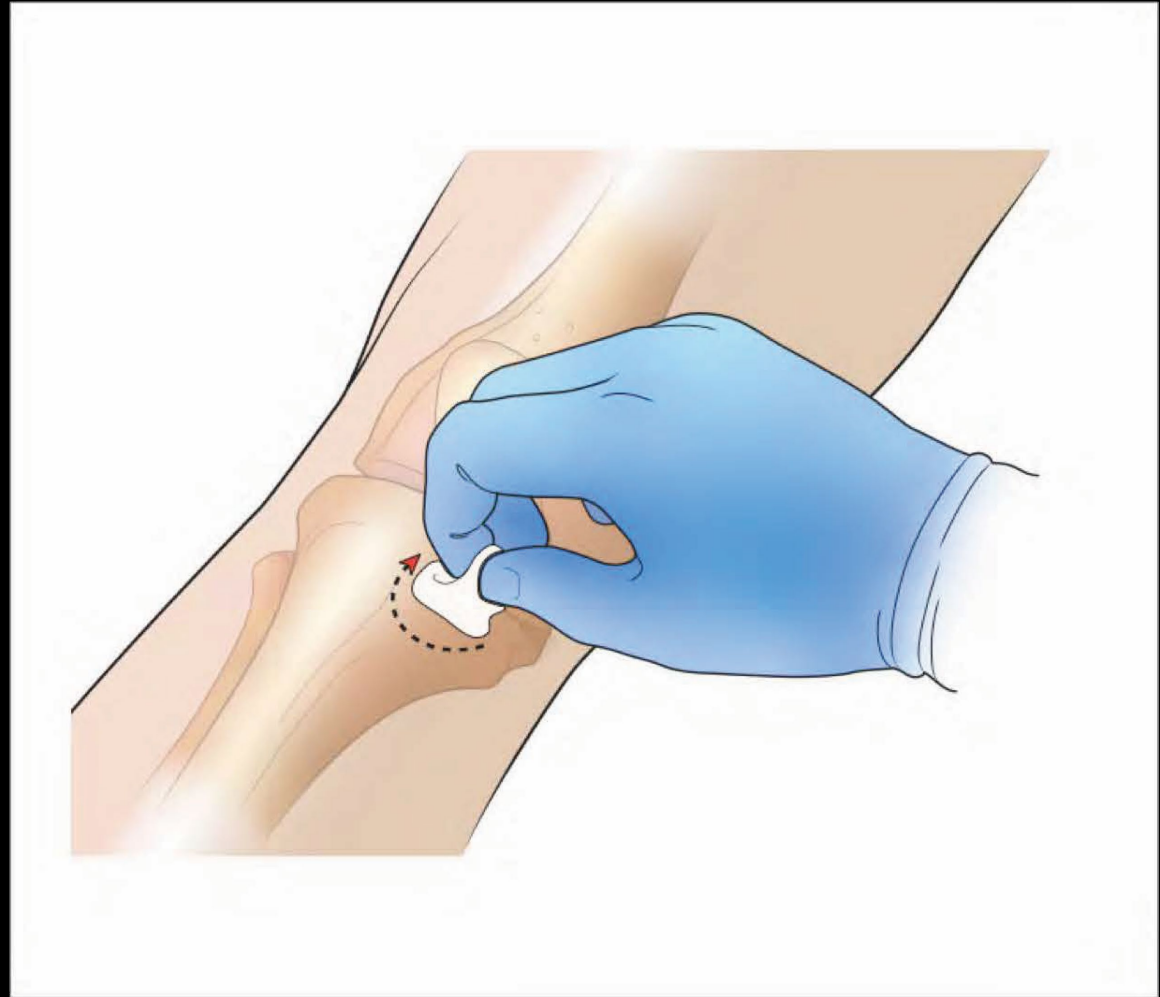
OBJECTIVE 4:

List steps for proper SAM IO® access.

INSERTION STEPS

STEP 1

Cleanse insertion site according to institutional protocol or policy.



STEP 2

PREPARE SUPPLIES:

PPE, driver, appropriately-sized needle assembly, NeedleVISE®, and tubing.

- 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.

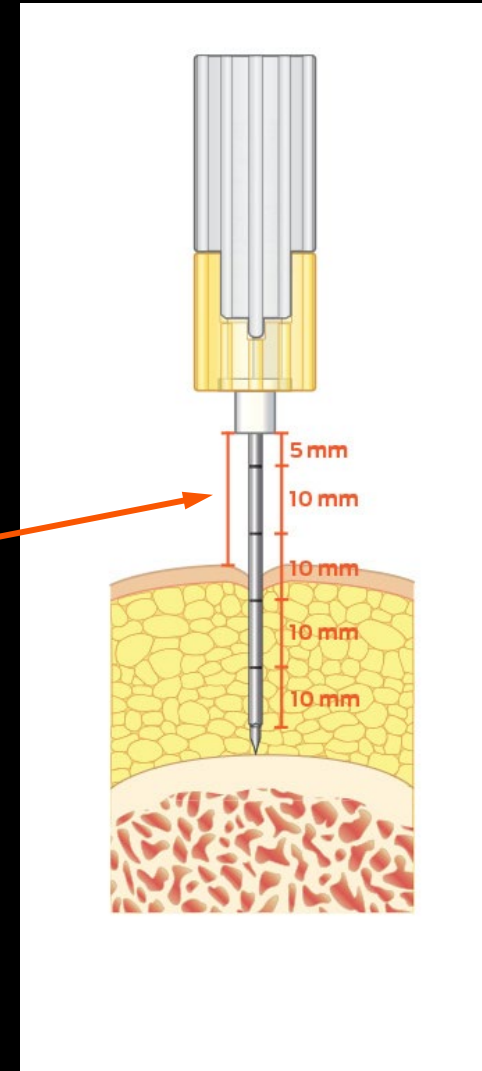


STEP 3

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

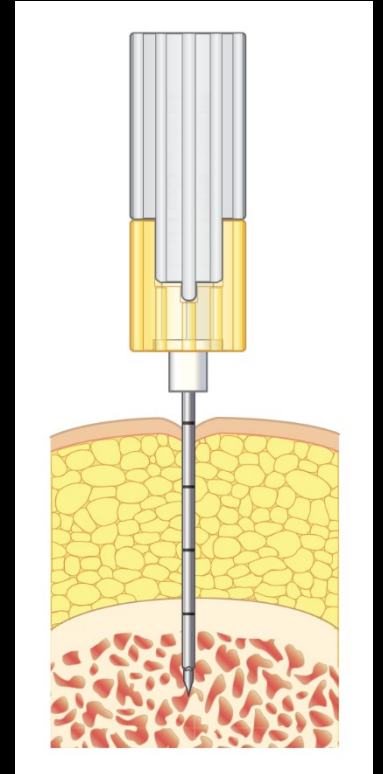
STEP 4

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



STEP 5

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



STEP 5 (Cont.)

IMPORTANT: DO NOT USE EXCESSIVE FORCE.

Use minimal (gentle) steady downward insertion pressure.

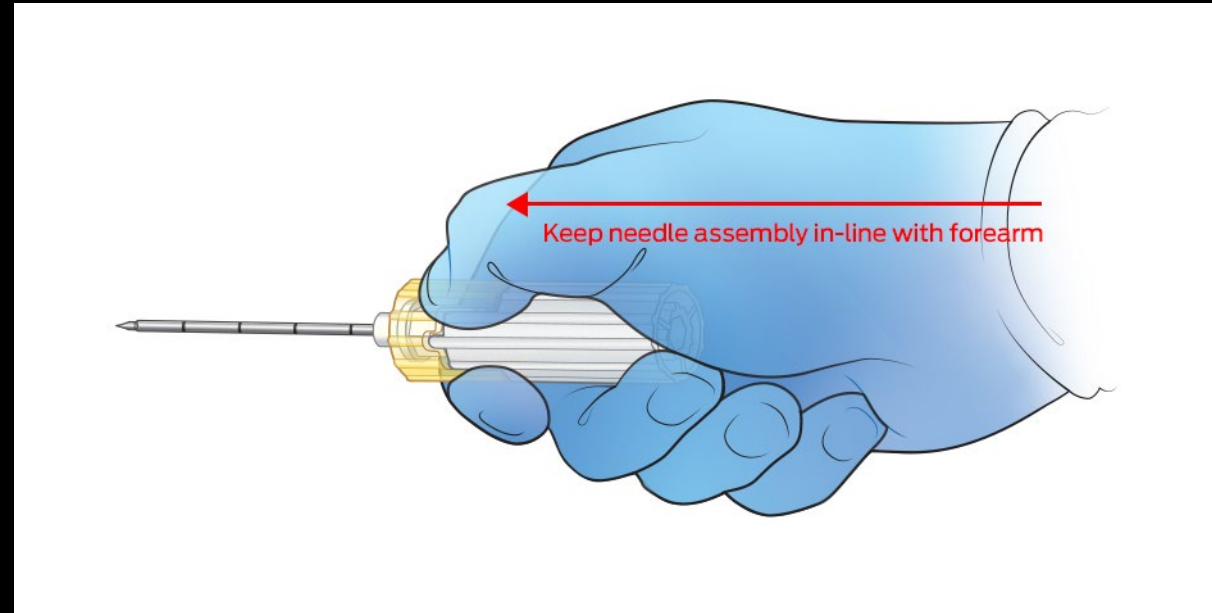
Allow needle assembly tip rotation to penetrate compact bone.

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.

OPTIONAL MANUAL INSERTION

If driver is unavailable, a manual insertion technique can be applied.

While holding needle assembly hub as illustrated, offer gentle downward pressure, while alternately rotating (twisting back and forth) to advance tip into medullary space.

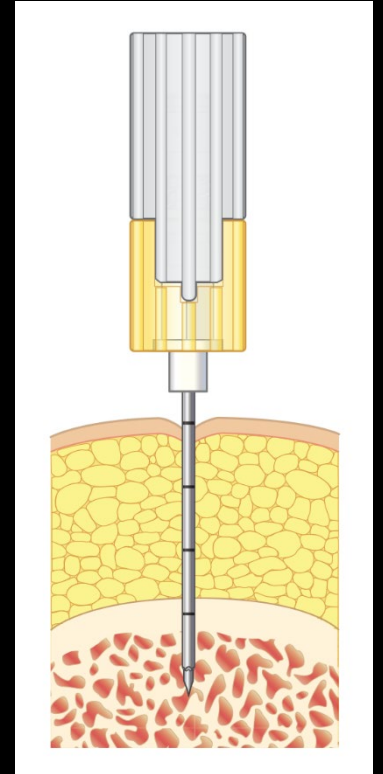


IMPORTANT: Do NOT use excessive force, and do NOT rock or bend needle assembly during insertion.

STEP 6

Advance needle assembly into desired position.

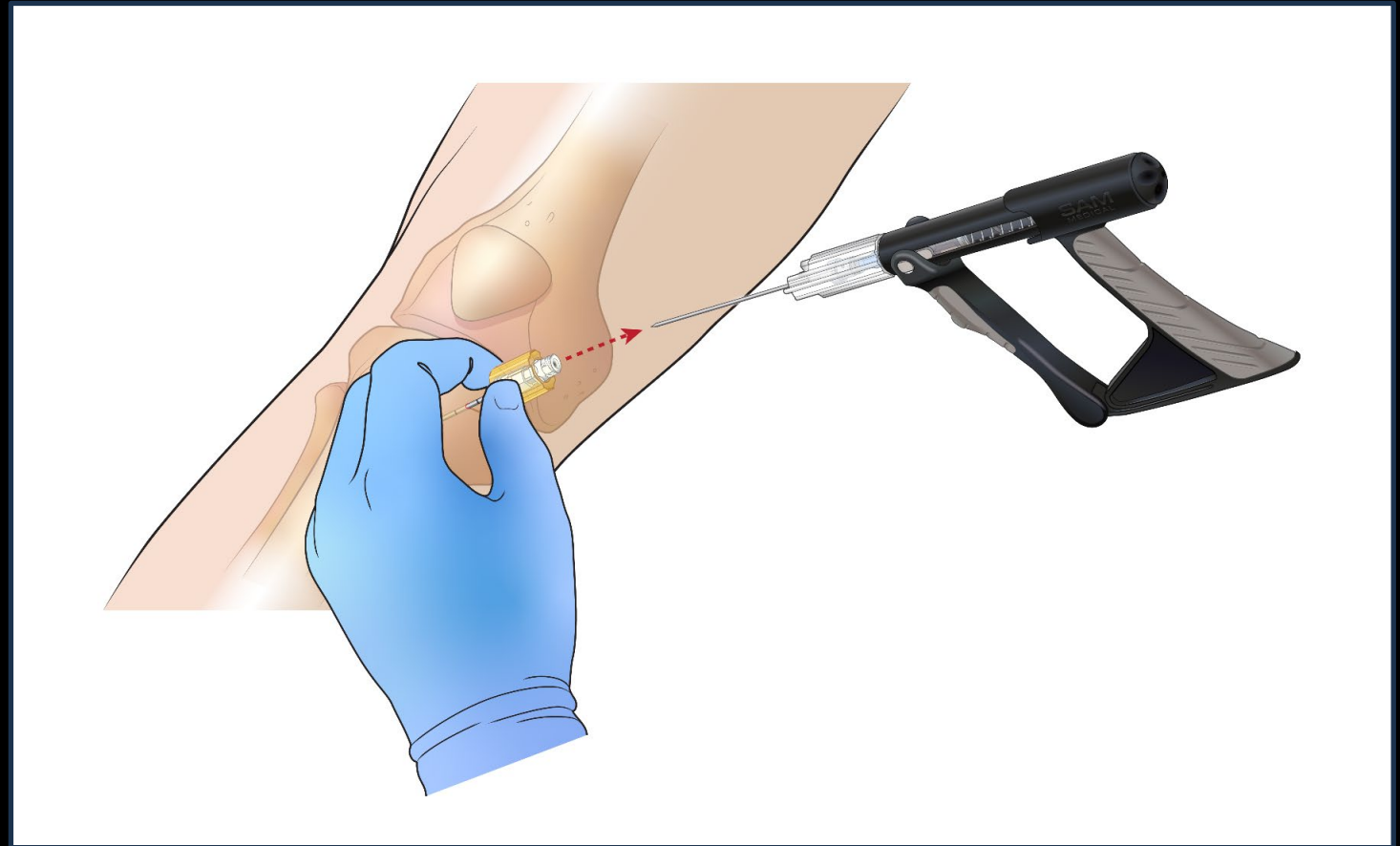
- For adult and pediatric insertions: Discontinue trigger actuation when subtle “give” or “pop” is appreciated, indicating needle assembly entry into medullary space.



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

STEP 7

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



STEP 8

While holding the driver
guide the stylet into
provided NeedleVISE[®] or
appropriate sharps
containment device and
disconnect stylet from
driver.



STEP 8 (Cont.)

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).

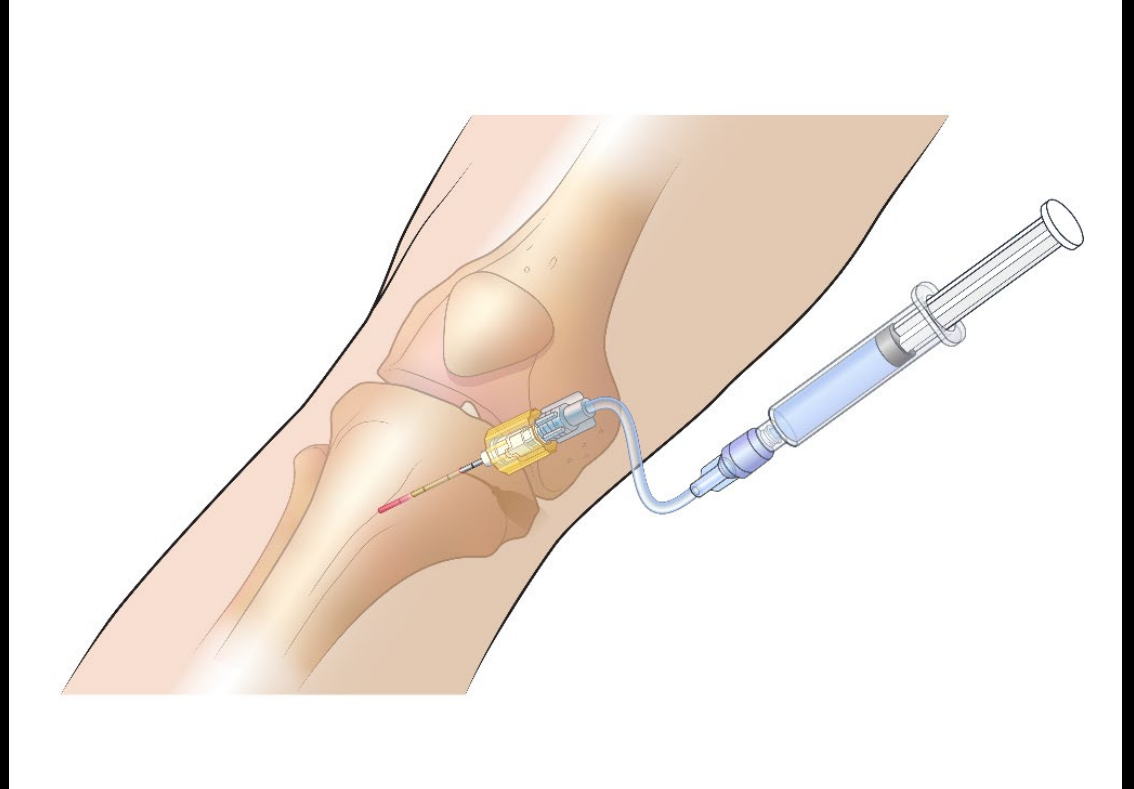
STEP 11

Attach primed extension set to catheter hub, firmly secure by twisting clockwise.

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

OBJECTIVE 5:

Describe indicators of successful SAM IO® placement.

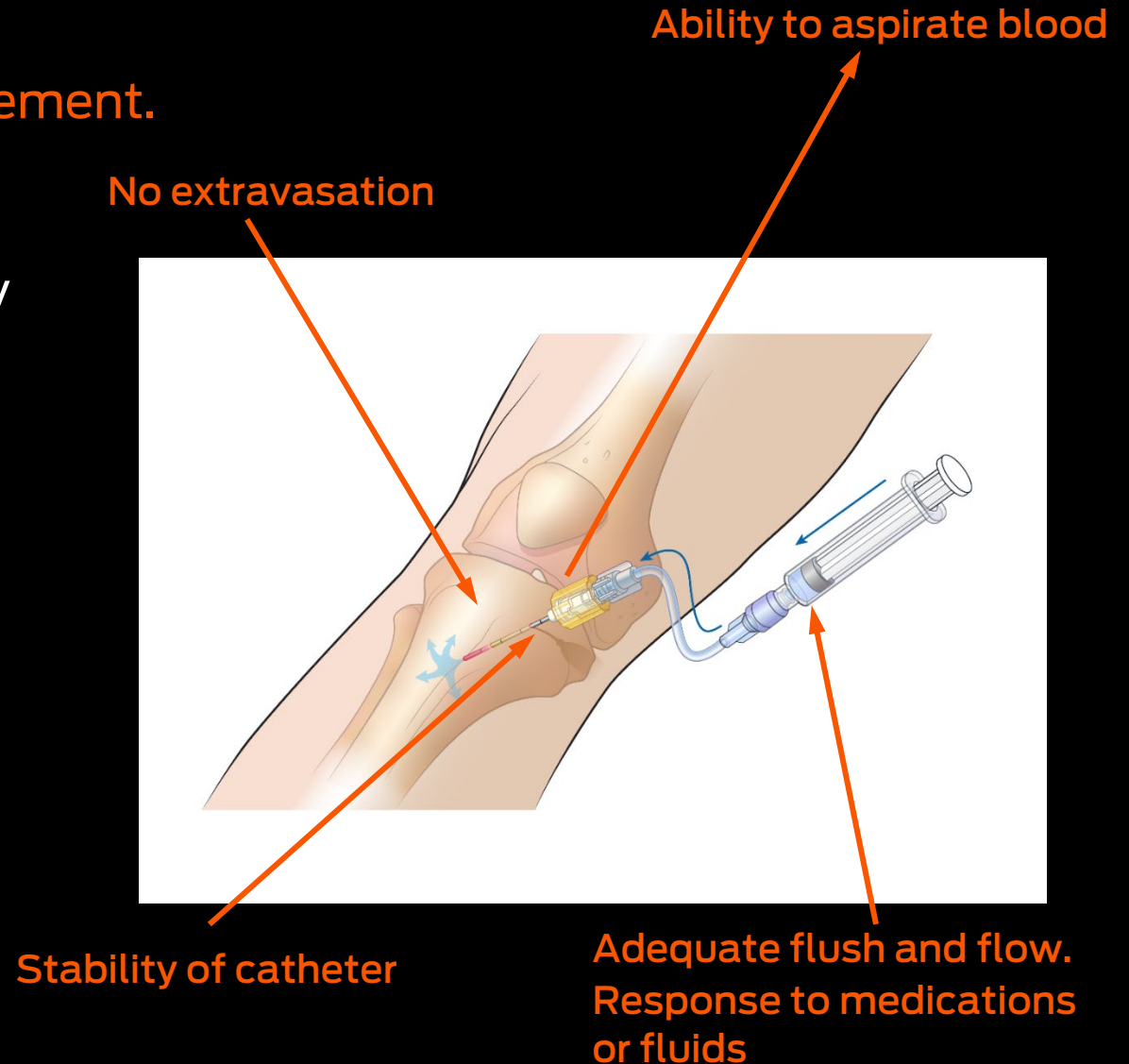
STEP 14

Flush SAM IO® with normal saline as directed by protocol or standard. Repeat flush as needed.

- Prior to flush, aspirate SAM 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.



OBJECTIVE 6:

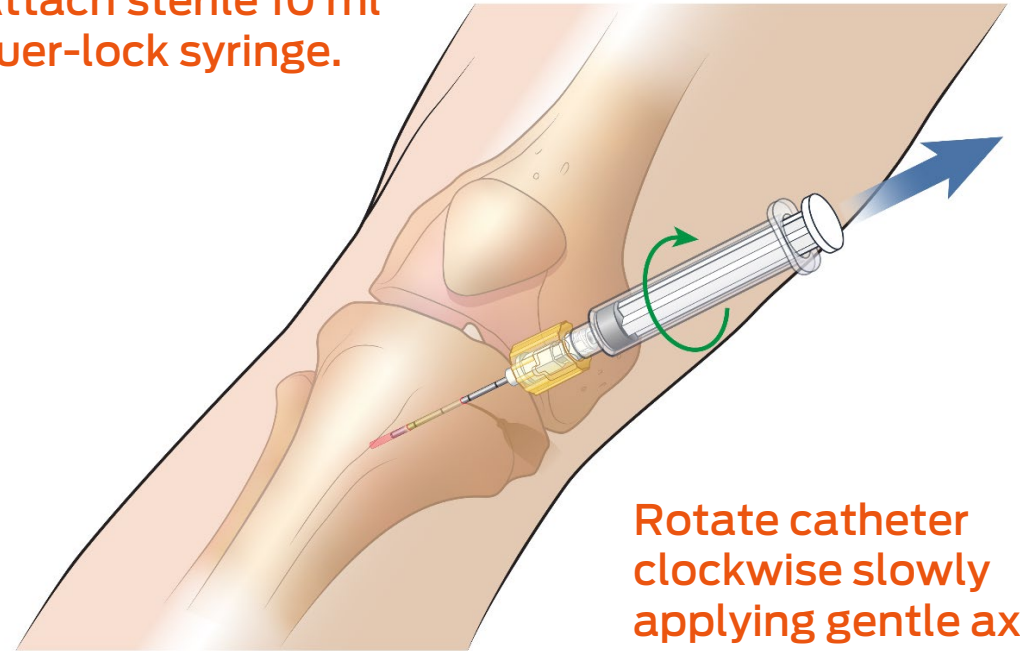
Demonstrate method for SAM IO® removal

STEP 15

To remove SAM IO® catheter from patient:

- 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.

Disconnect extension set.
Attach sterile 10 ml
Luer-lock syringe.

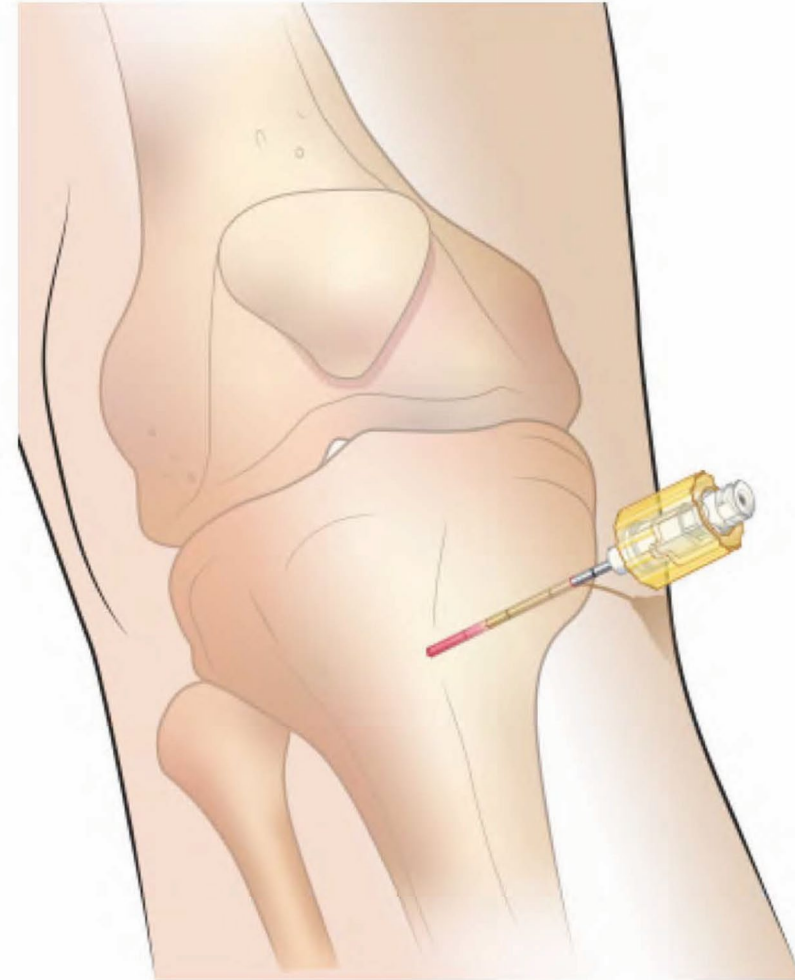


Rotate catheter
clockwise slowly
applying gentle axial
traction.

SAM 10[®] STABILIZER

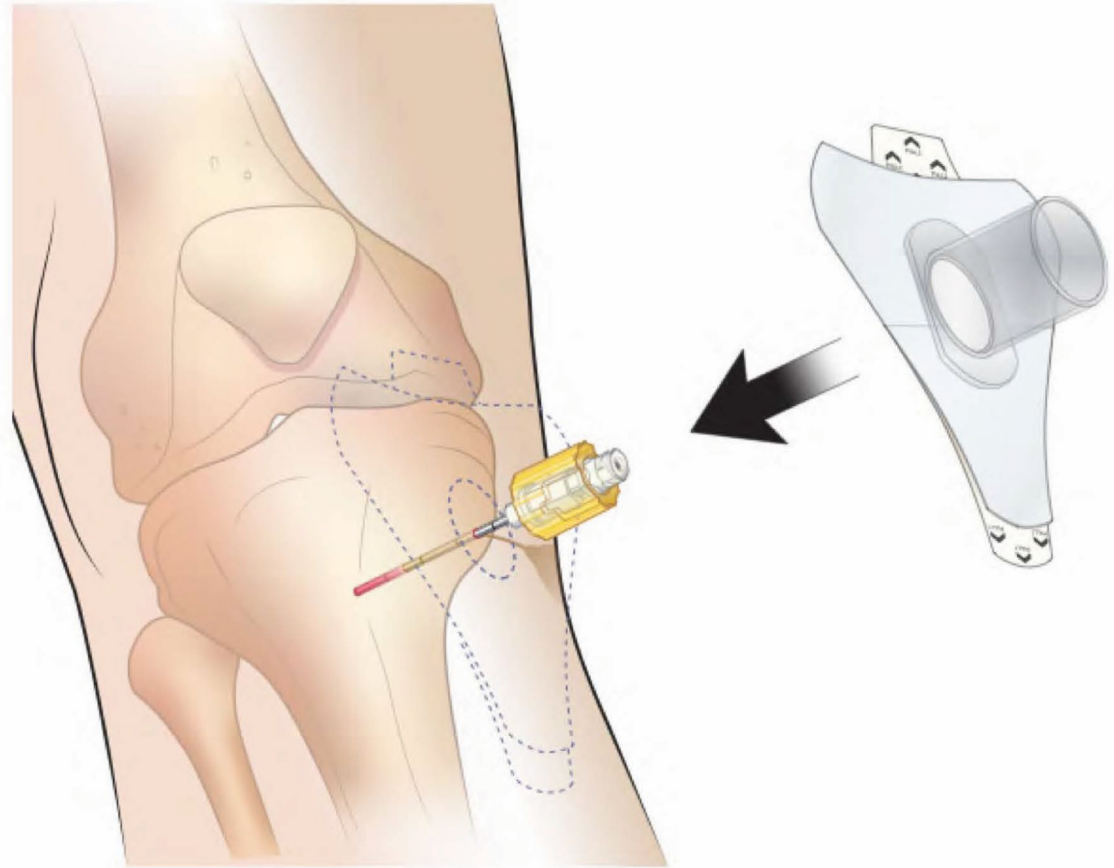
STEP 1

With SAM IO[®] catheter in position, consider use of SAM IO[®] Stabilizer.



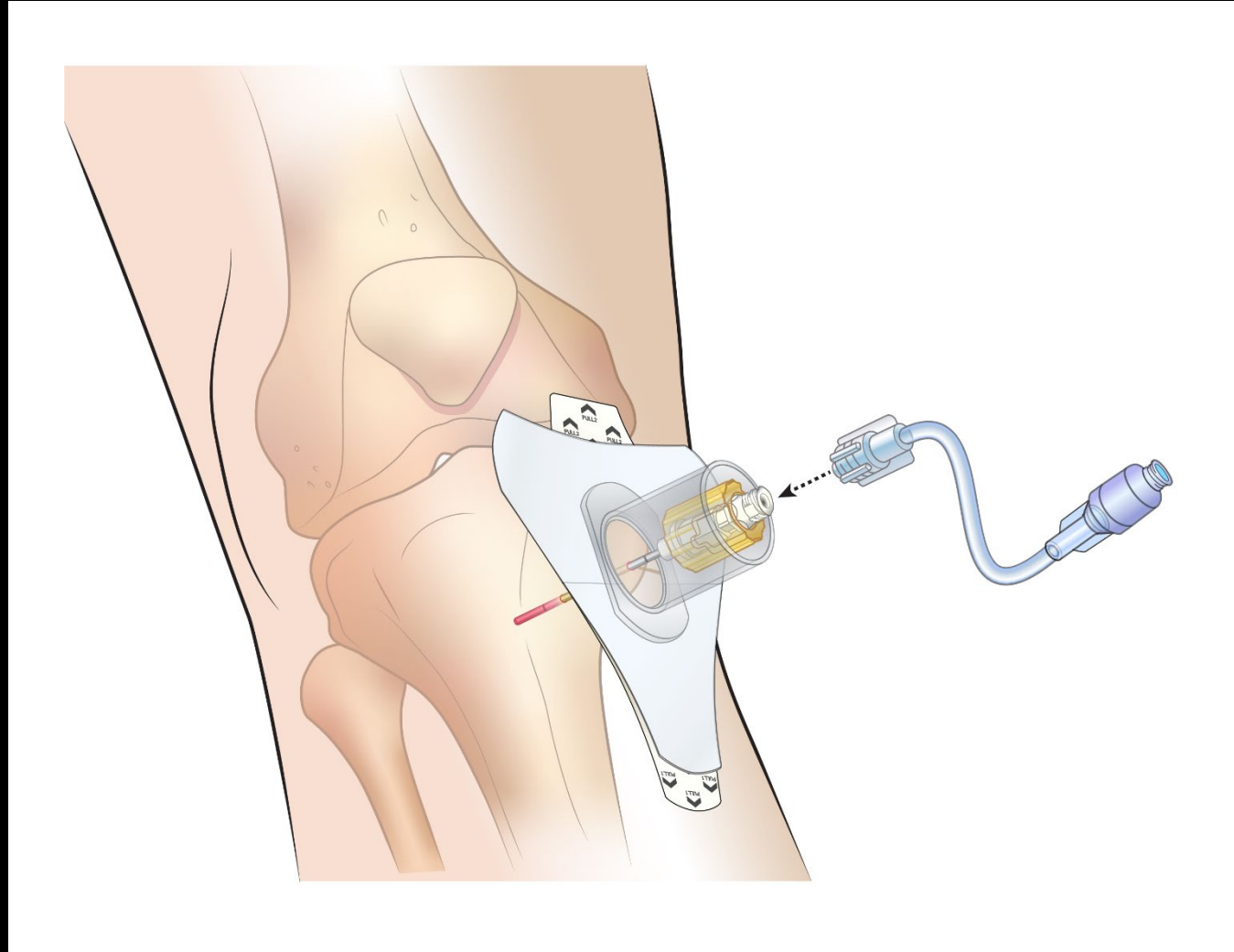
STEP 2

Place sterile SAM IO®
Stabilizer carefully over
catheter and against skin.



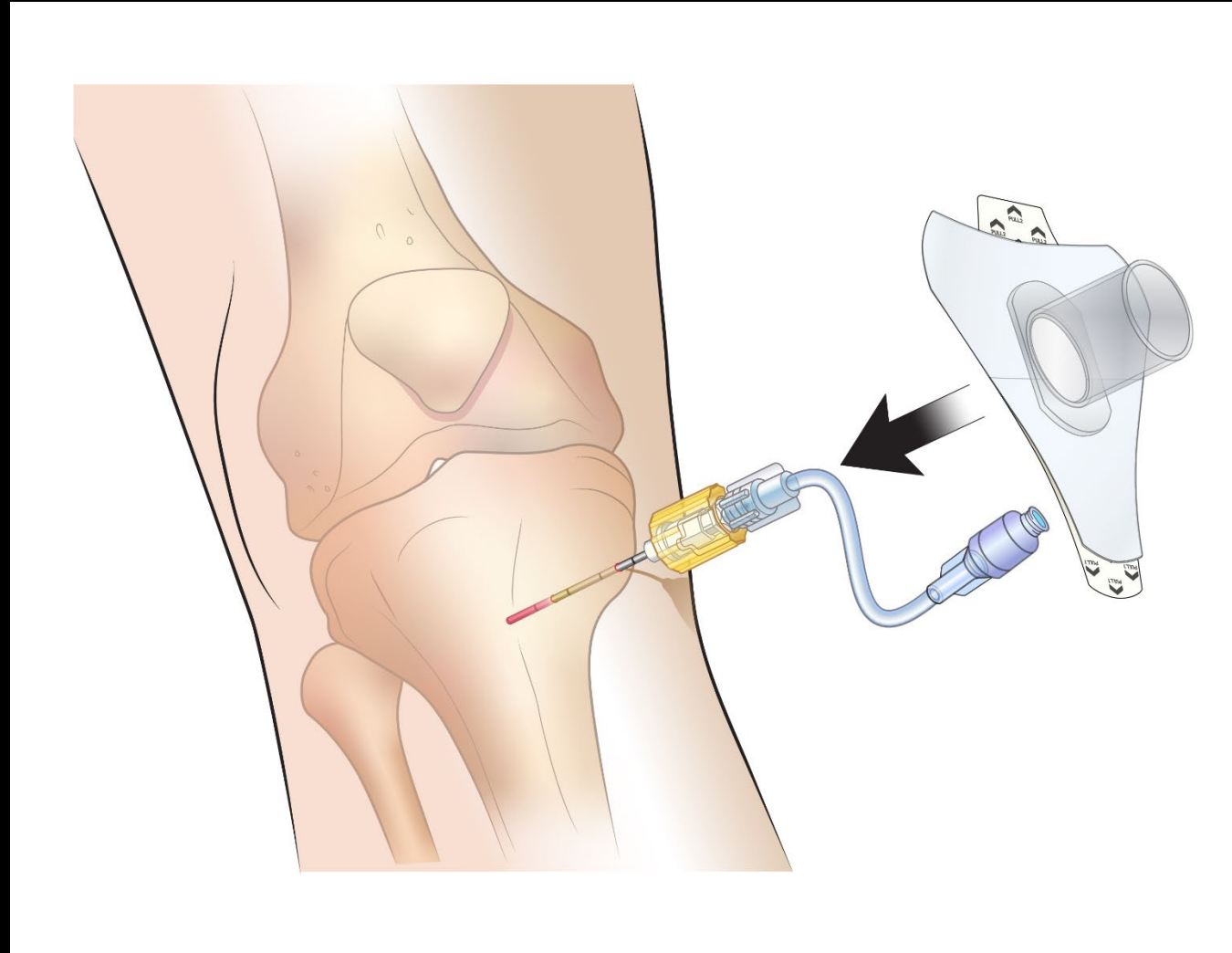
STEP 3

Attach primed extension set to SAM IO[®] Catheter.
KEY POINT: Extension set design permits single-handed tightening to catheter.



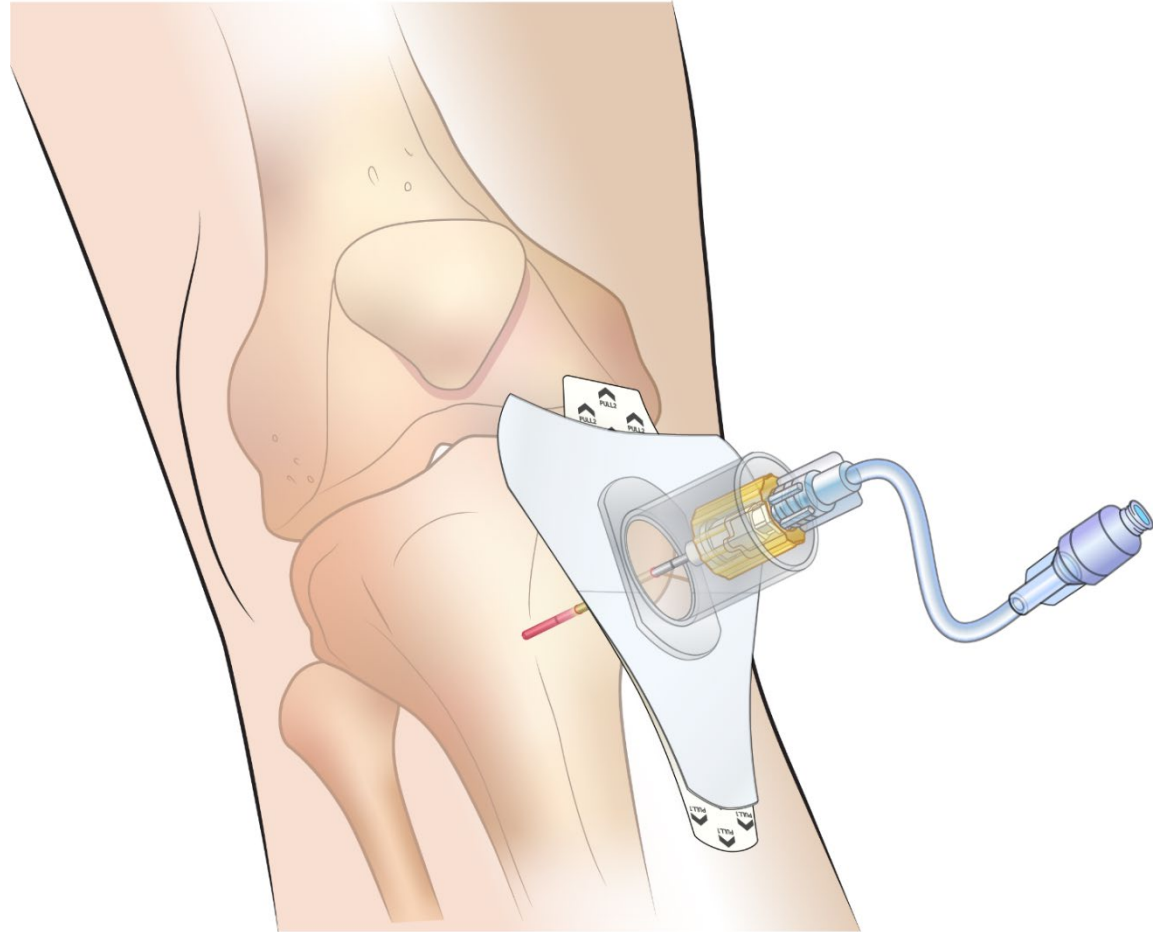
OPTIONAL APPLICATION METHOD

With attached extension set in position, gently feed extension set through SAM IO® Stabilizer. Guide SAM IO® Stabilizer over catheter, and against patient skin.



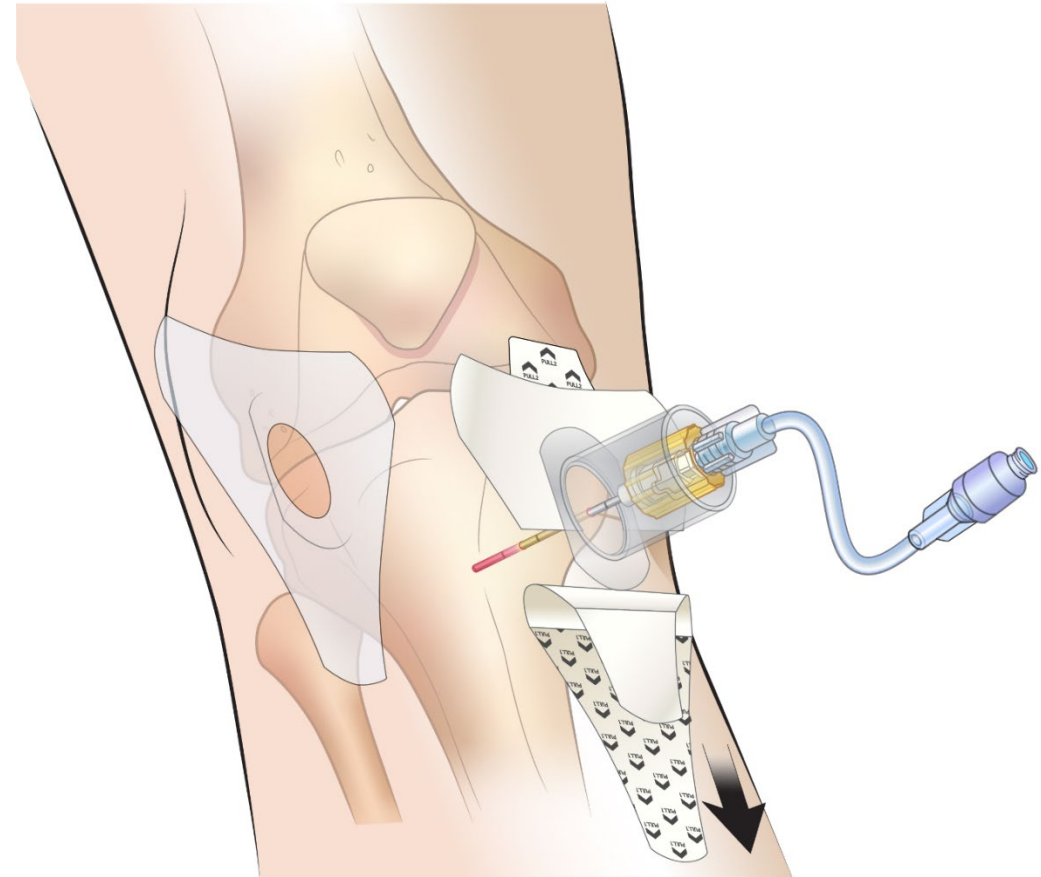
STEP 4

Ensure SAM IO® Catheter
is centered within
SAM IO® Stabilizer



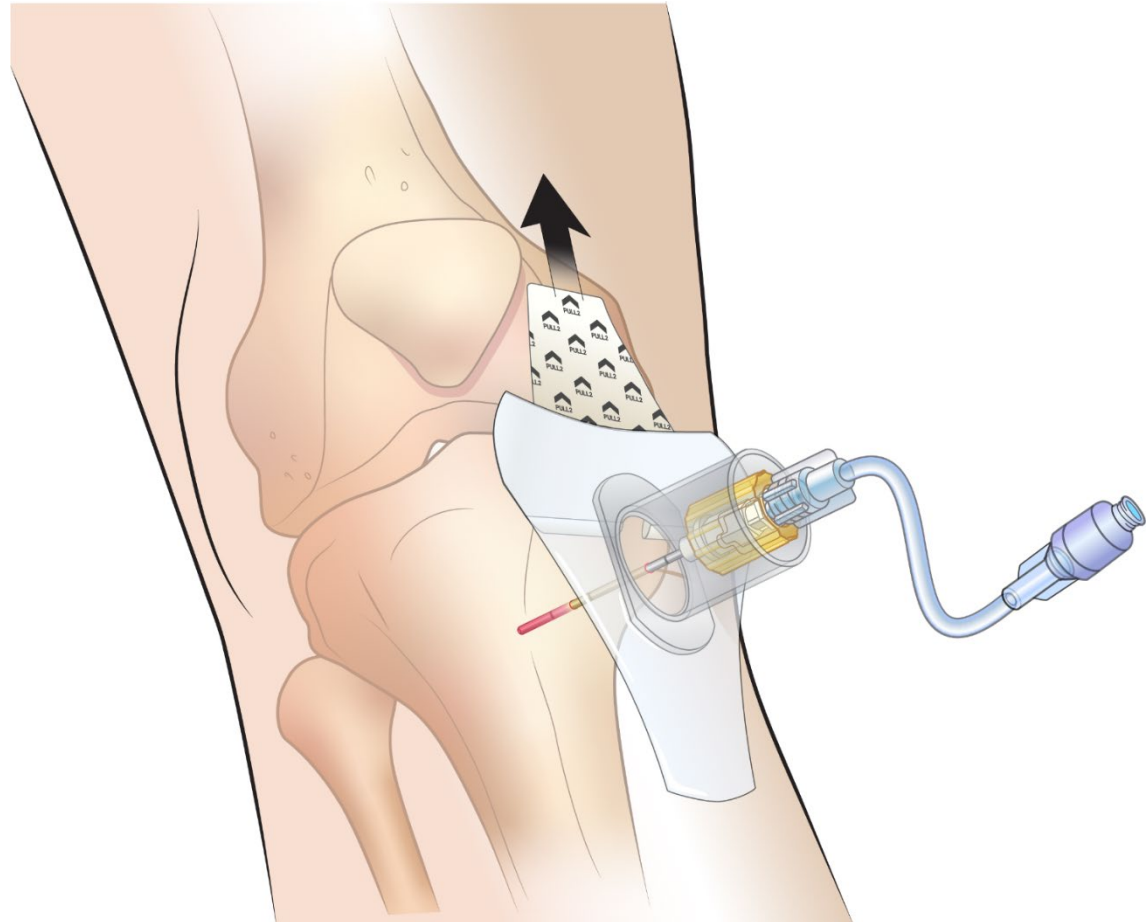
STEP 5

Hold SAM IO® Stabilizer in position and gently pull Tab 1. By pulling Tab 1 you are removing adhesive backing. This will expose adhesive to patient skin. Gently press exposed adhesive against patient skin.



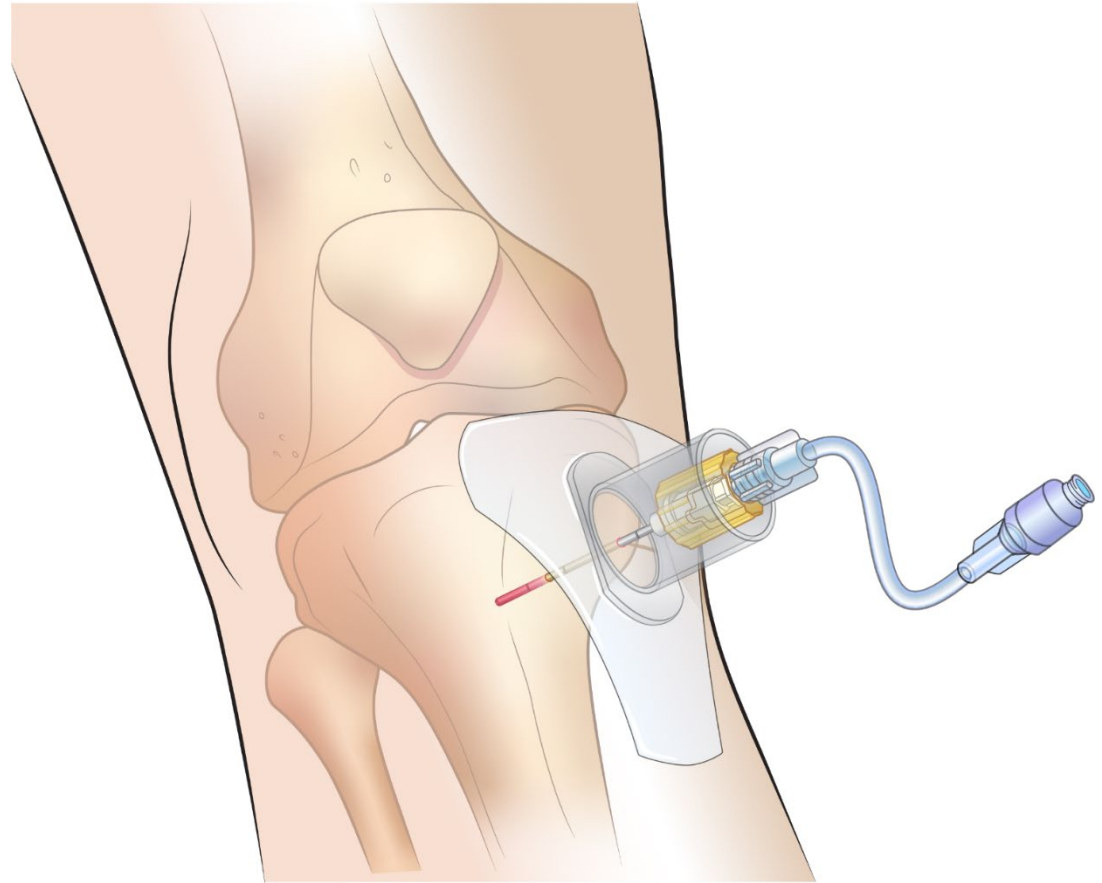
STEP 6

Hold SAM IO® Stabilizer in position and gently pull Tab 2. By pulling Tab 2, you are removing adhesive backing. This will expose adhesive to patient skin. Gently press exposed adhesive against patient skin.



STEP 7

With SAM IO® Stabilizer in position (and adhesive backing removed) gently smooth all exposed adhesive to patient skin.



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Special thanks to the Centre for Emergency Health Sciences