



WARRANTY: SAM IO® access system is a medical device. SAM MEDICAL® warrants the SAM IO® as merchantable expressly for the indications detailed. SAM MEDICAL® disclaims all other implied warranties relating to this product, which includes use beyond this product's identified purpose, and utilization by untrained personnel or legally unauthorized parties.

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: Federal Law restricts SAM IO® to sale by, or on the order of, a licensed physician.

A PRECAUTIONS, WARNINGS & ADVISORIES

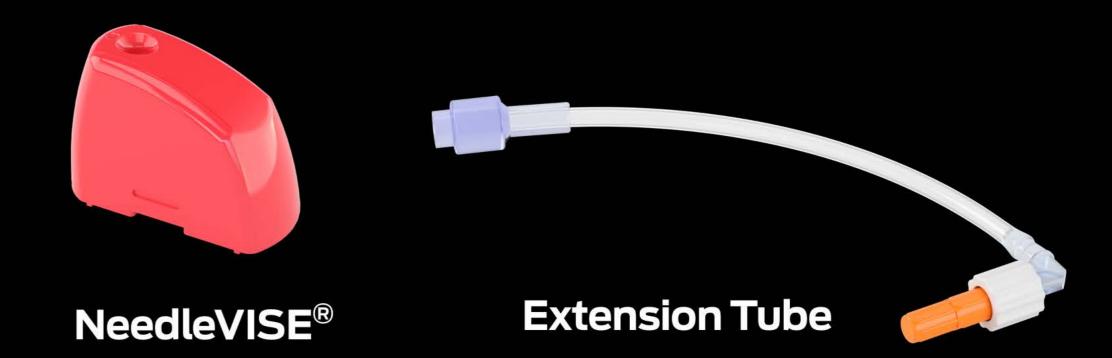
- Stylet and catheter (needle assembly) are NOT MRI compatible.
- Assess skin, adipose, and muscle thickness before IO insertion.
- Use aseptic technique.
- Needle assembly is single use only.
- Do not recap needle assembly or reconnect separated components.
- Re-use of contents supplied sterile may cause illness or injury.
- Minimize or restrict patient movement during insertion.
- Care should be taken during insertion and treatment when IO use for patients who have bone diseases that increase the likelihood of fracture, extravasation, or dislodgement.
- Use biohazard and sharps disposal precautions.
- Monitor insertion site frequently for extravasation.
- Do not leave IO catheter inserted for more than 24 hours.
- 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 function.
- 2. List indications and contraindications for IO access.
- 3. Identify landmarks for IO access.
- 4. List steps for proper SAM IO® access.
- 5. Describe indications of successful IO placement.
- 6. Demonstrate method for IO removal.

Identify SAM IO® components and function.





Stabilizer

15 mm Needle

25 mm Needle 45 mm Needle

Driver

Identify SAM IO® components and function.

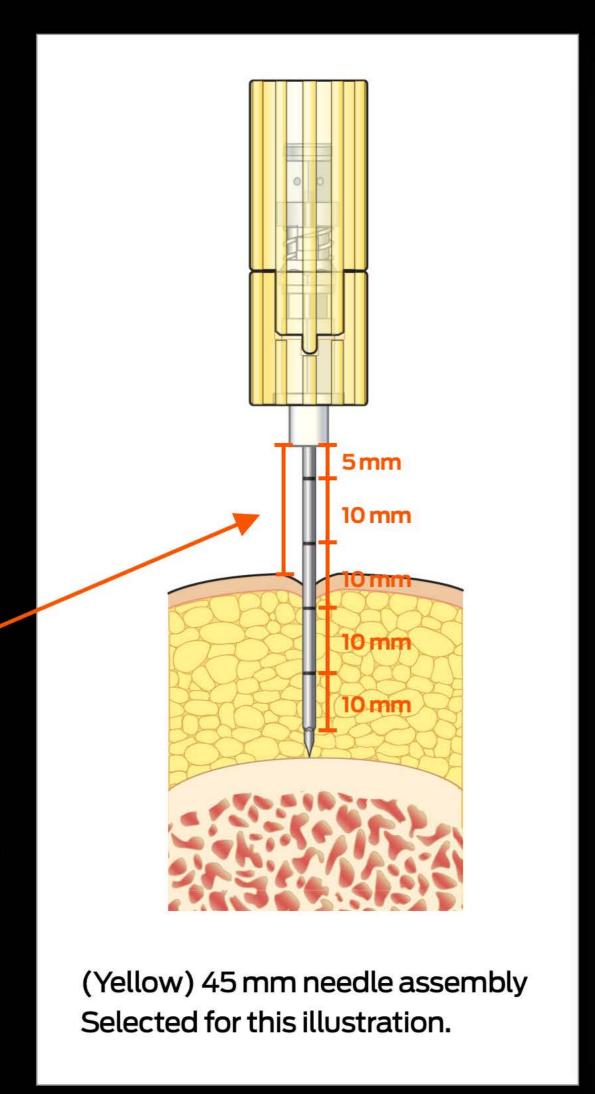


Remove SAM IO® Driver from box.

Identify SAM IO® components and function.

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

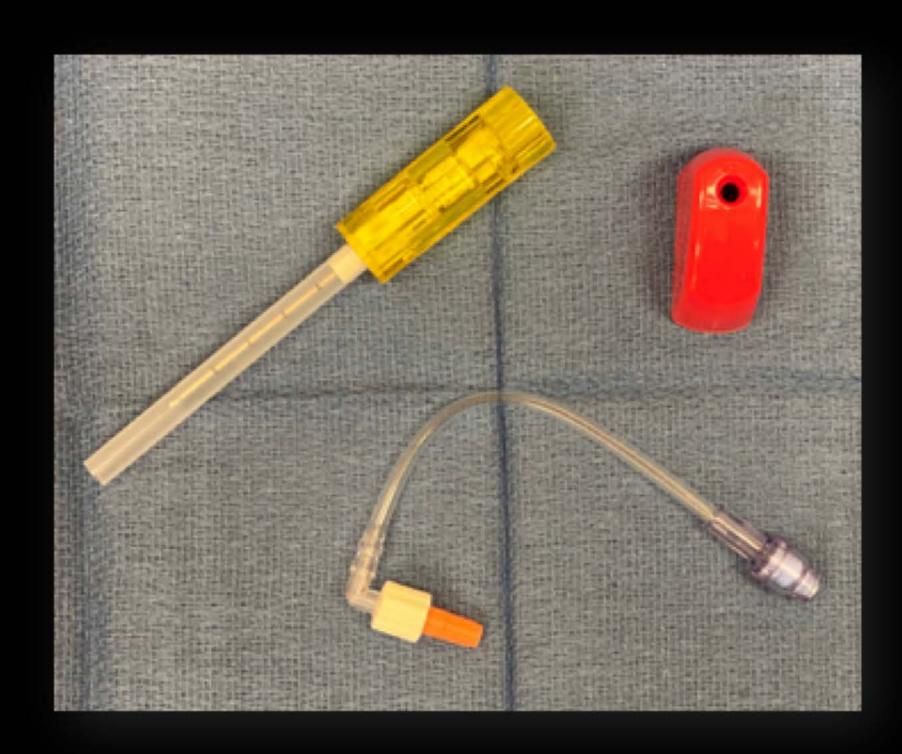
Ensure ≥ 5 mm of needle assembly visible above skin (with assembly touching periosteum) before attempting IO insertion.





Identify SAM IO® components and function.

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





45 mm needle assembly selected for this training program.

List Indications and Contraindications for IO access.

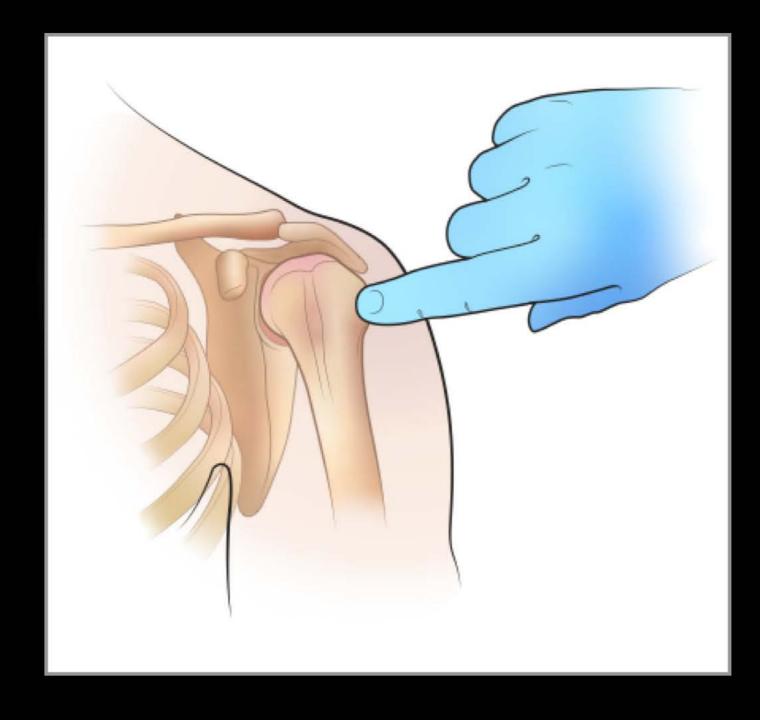
INDICATION:

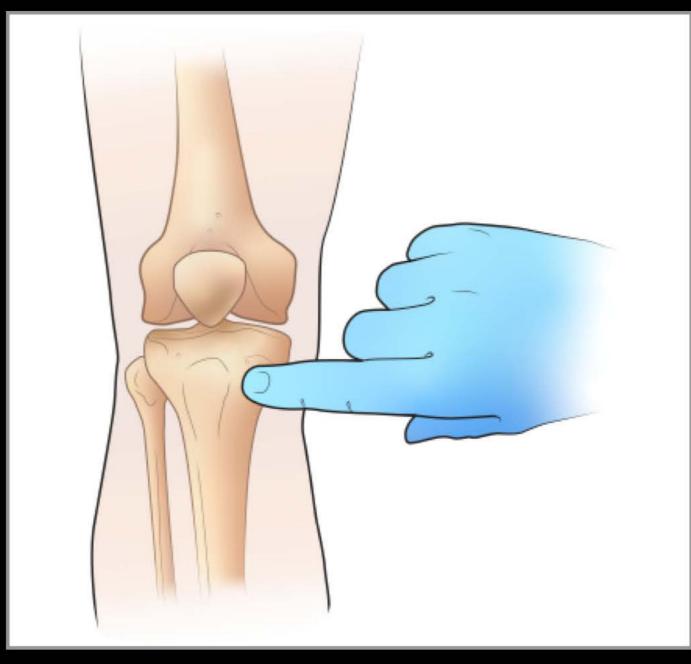
For intraosseous access anytime in which vascular access is difficult to obtain in emergent, urgent, or medically necessary cases.

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.

Identify landmarks for IO access: ADULT







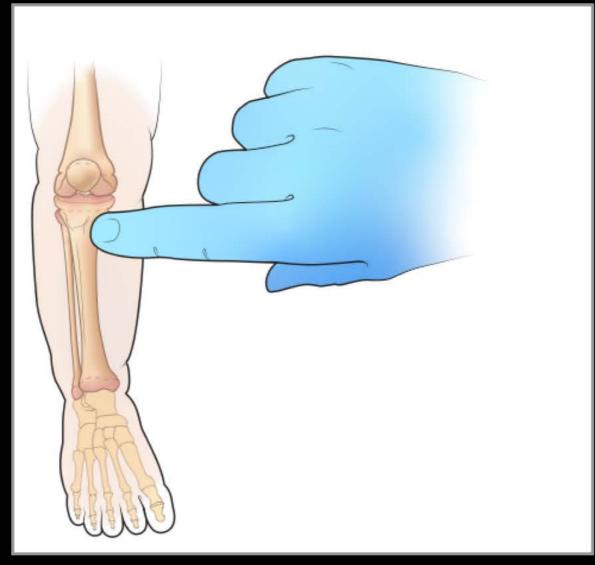
Proximal Humerus

Proximal Tibia

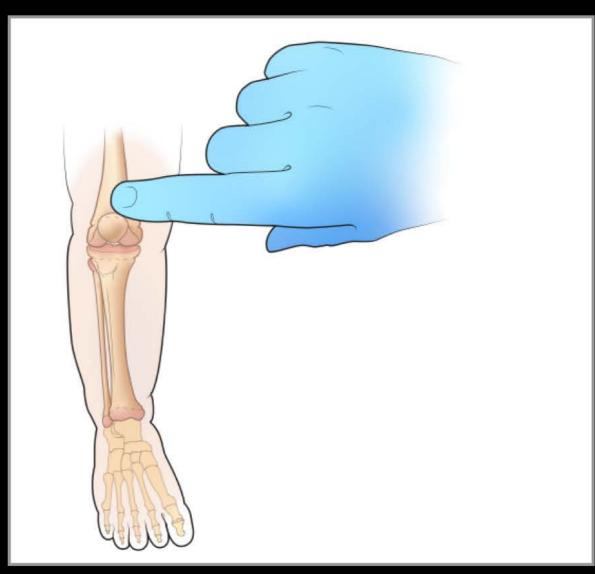
Distal Tibia

Identify landmarks for IO access: PEDIATRIC









Proximal Humerus

Proximal Tibia

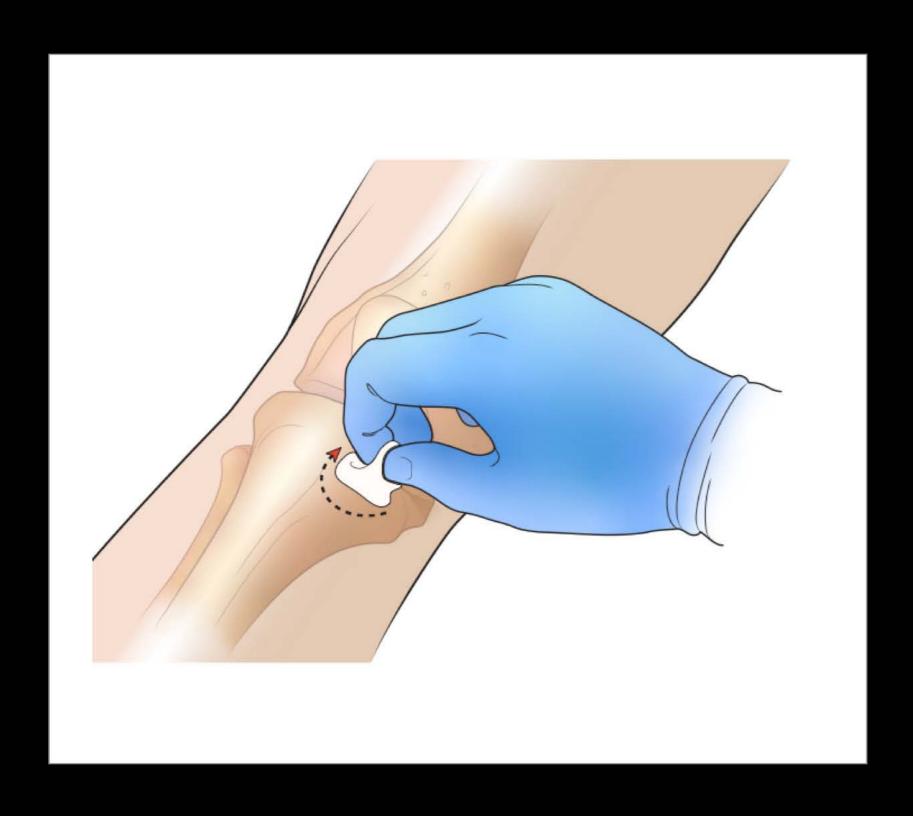
Distal Tibia

Distal Femur

List steps for proper IO access.

INSERTION STEPS

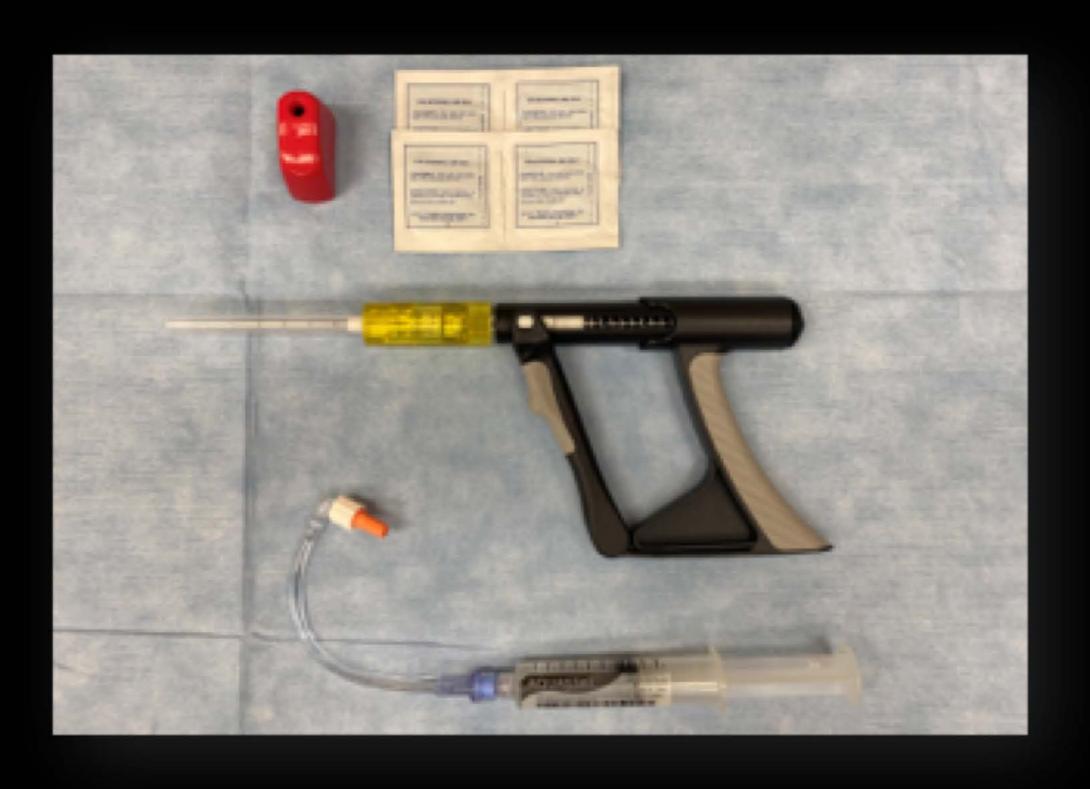
Cleanse insertion site according to institutional protocol or policy.



STEP 2

Prepare supplies.

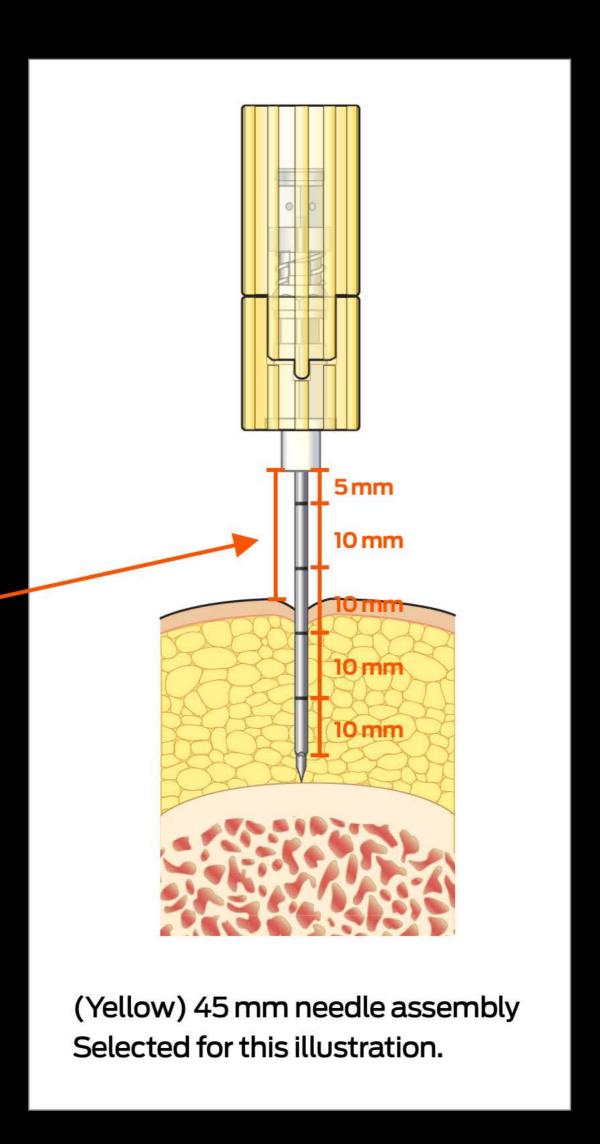
PPE, driver, appropriately-sized needle assembly, NeedleVISE®, primed extension set with saline flush, and suitable cleansing agent.



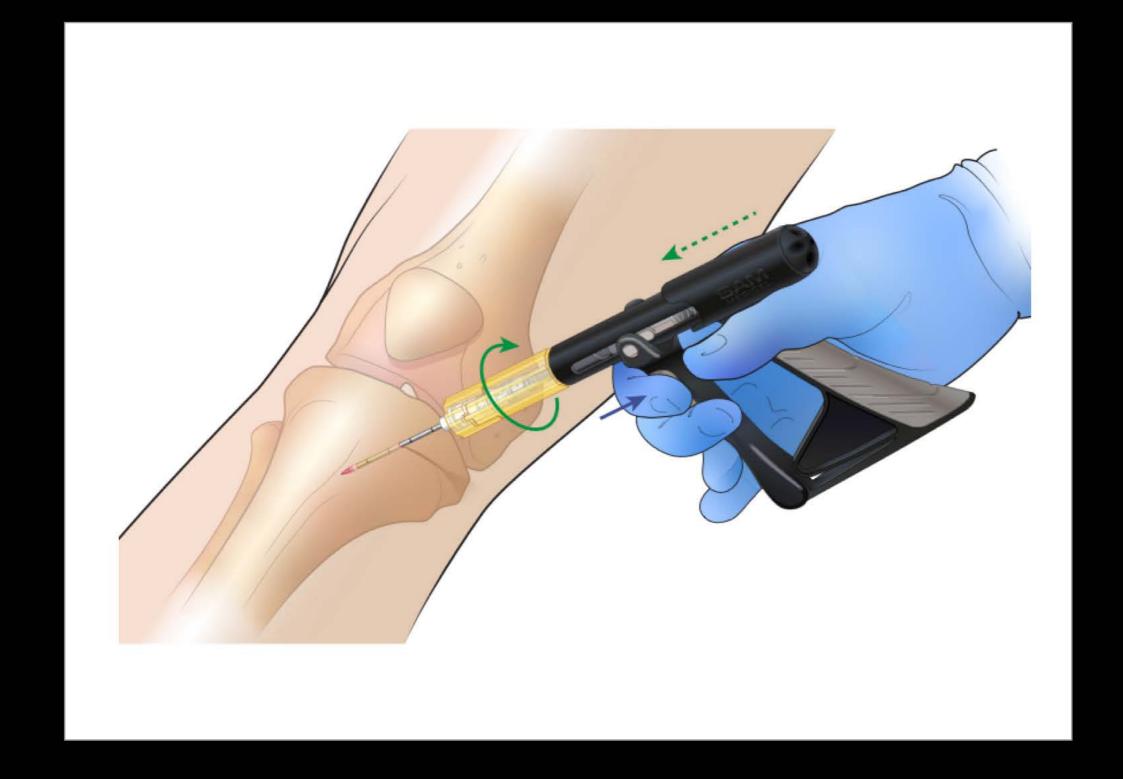
Insert needle assembly through skin and adipose tissue.

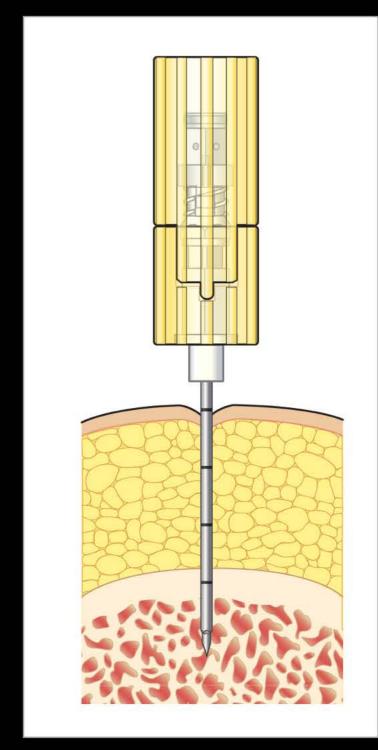
STEP 4

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



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

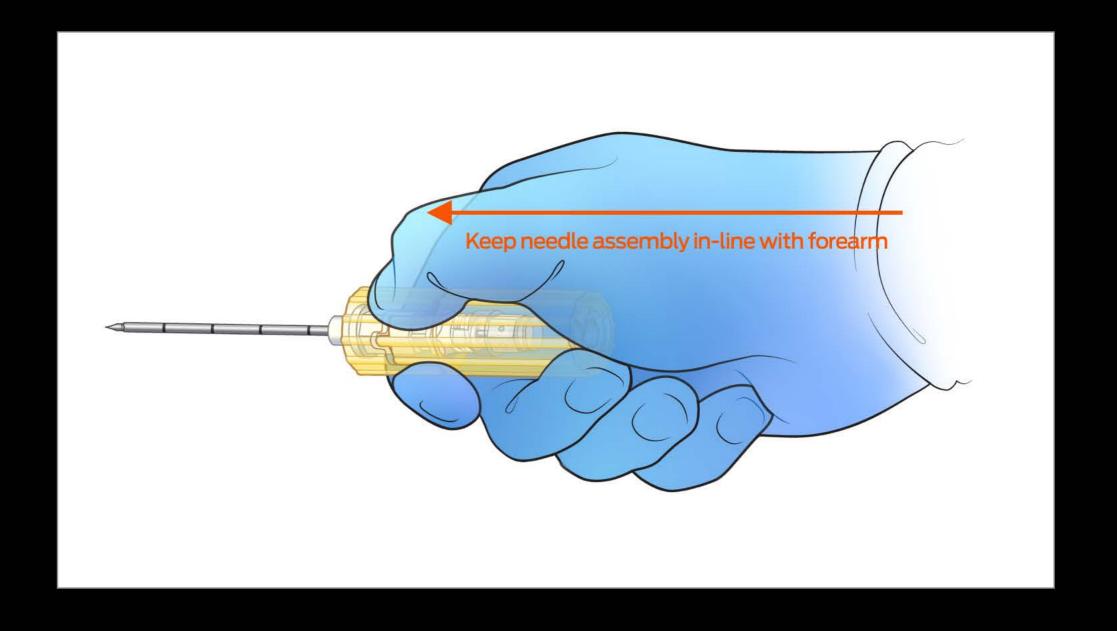




OPTIONAL MANUAL INSERTION

In the event of driver failure, grasp entire needle assembly and disconnect from driver.

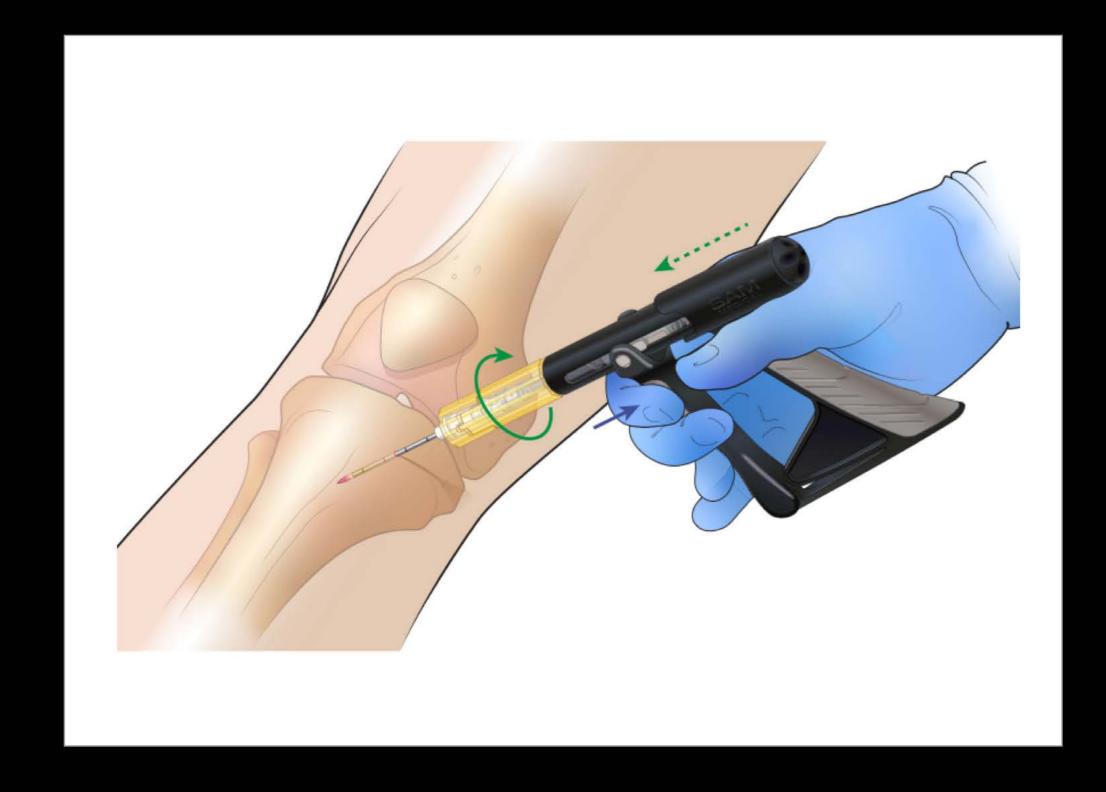
While holding needle assembly (as shown) use gentle downward pressure, while alternately rotating (twisting back and forth) to advance needle assembly into medullary space.

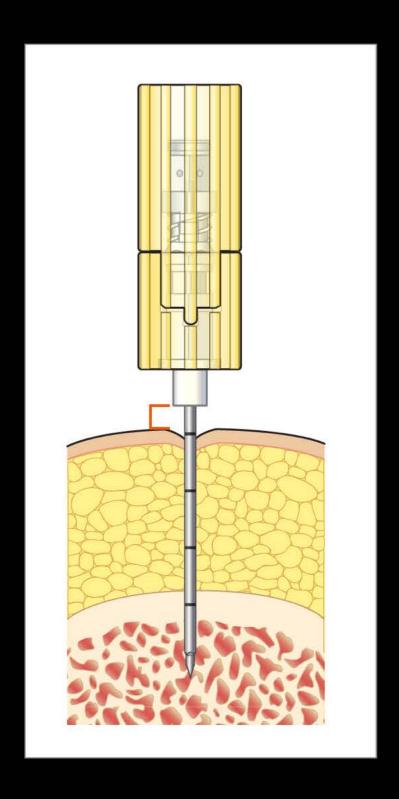


Advance needle assembly into desired position.

For adult and pediatric insertions:

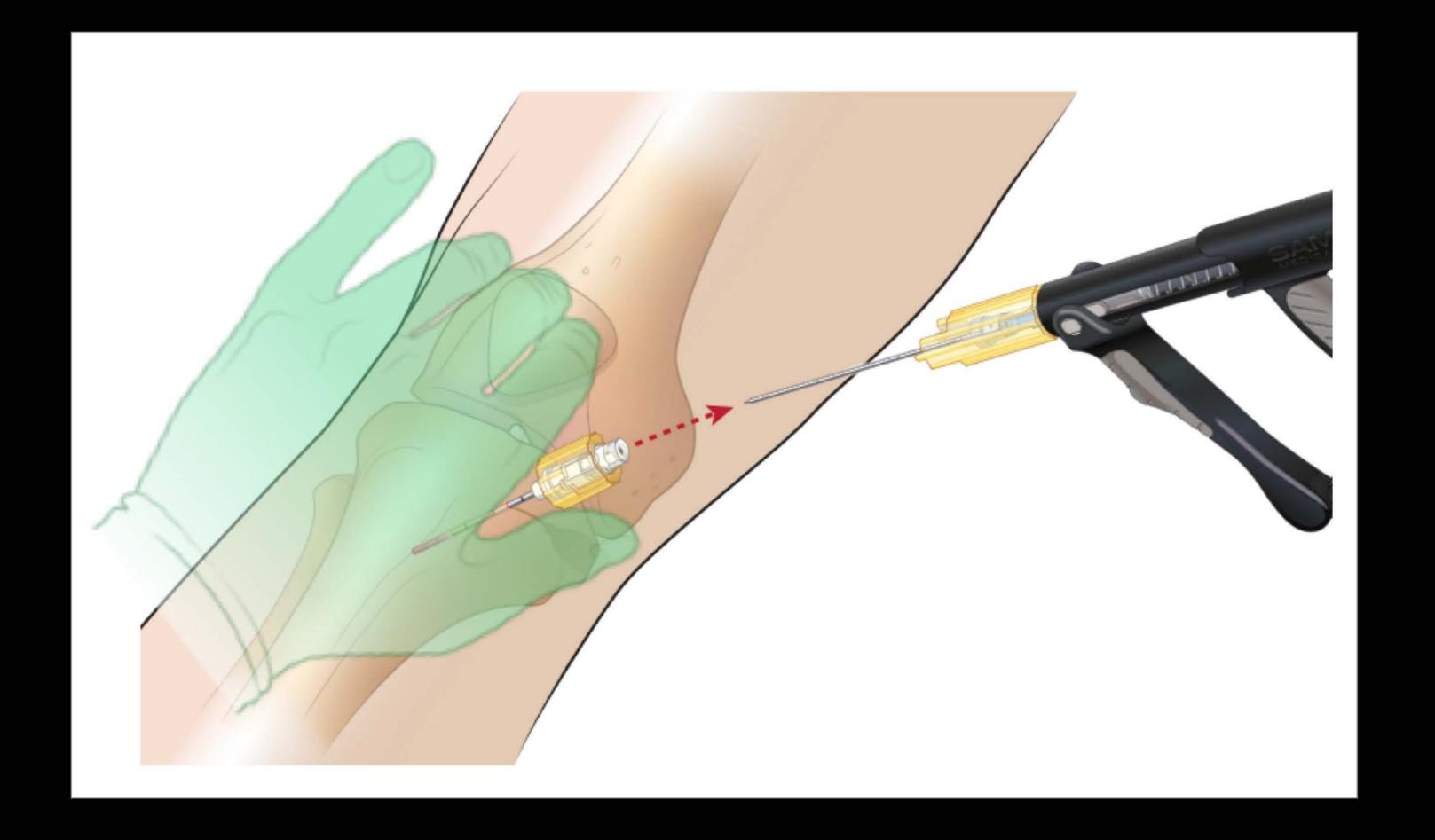
Discontinue trigger actuation when subtle "give" or "pop" is appreciated, indicating needle assembly entry into medullary space.



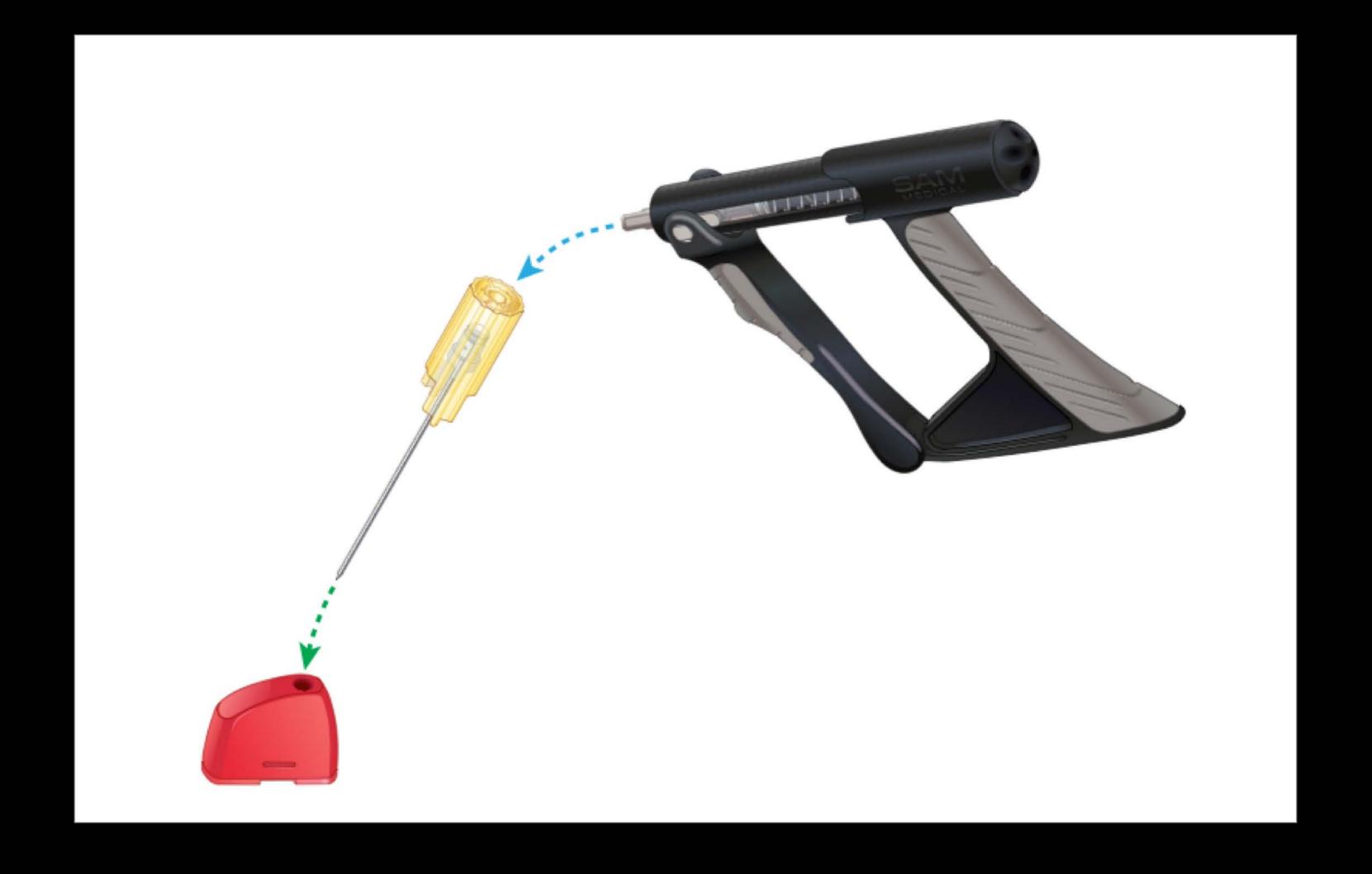


Remove stylet by stabilizing needle assembly hub while retracting (lifting off) and disconnecting driver.

Stylet will remain attached to driver.

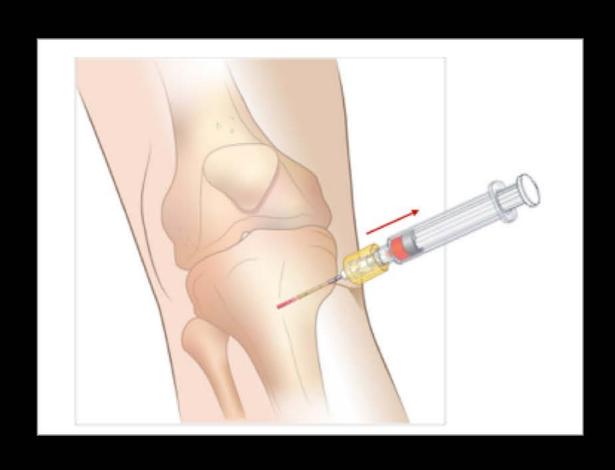


Disconnect stylet from driver after stylet has been inserted into provided NeedleVISE® or appropriate sharps containment device.



STEP 9 (OPTIONAL)

Obtain blood samples for laboratory analysis.

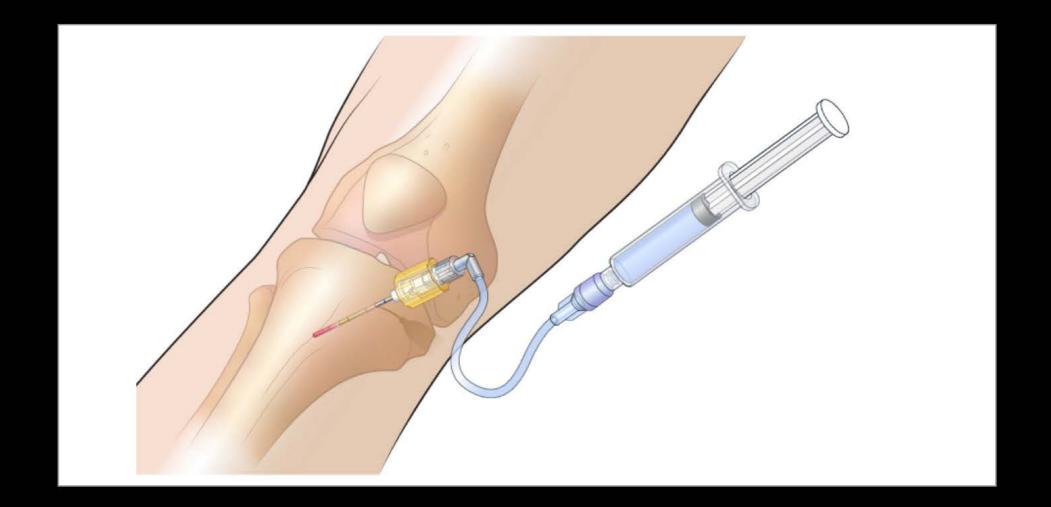


STEP 11 (OPTIONAL)

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

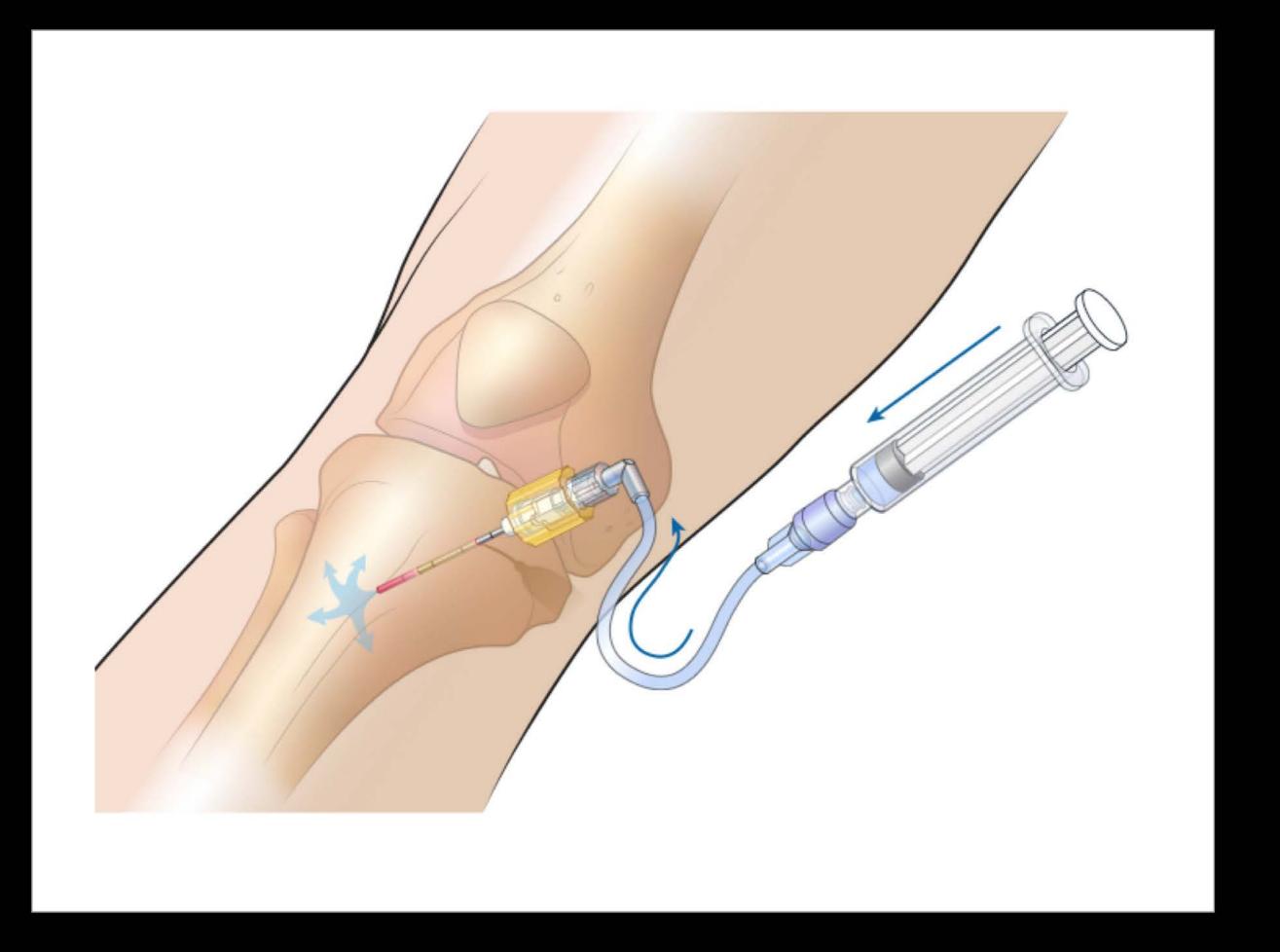
STEP 10

Attach primed extension set to catheter hub.



Confirm catheter placement with one or more methods:

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



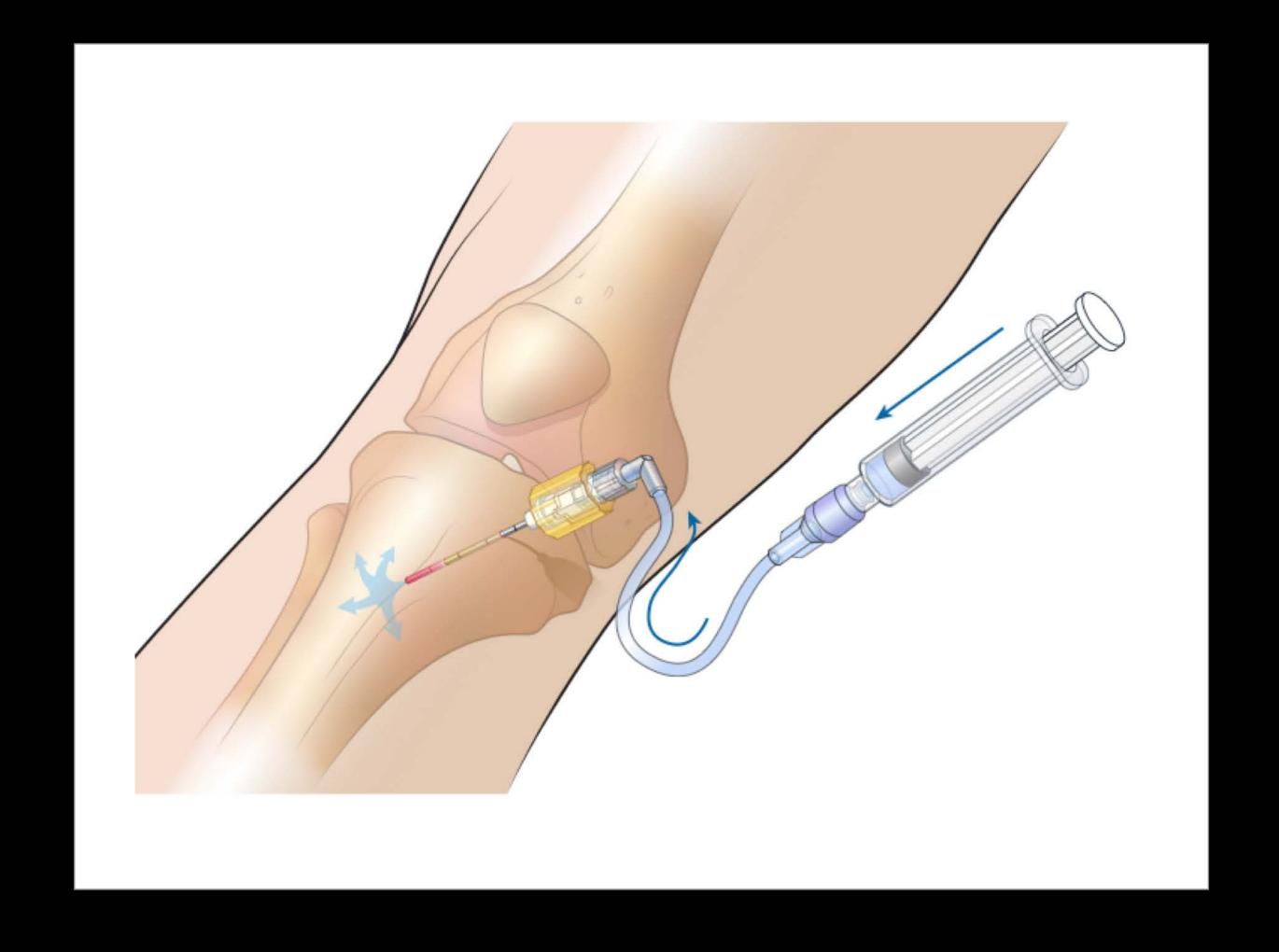
Flush IO catheter with normal saline as directed by protocol or standard.

Repeat flush as needed. Administer fluids or medications as indicated.

Prior to flush, aspirate IO catheter for visual confirmation of blood.

Monitor insertion site frequently for extravasation.

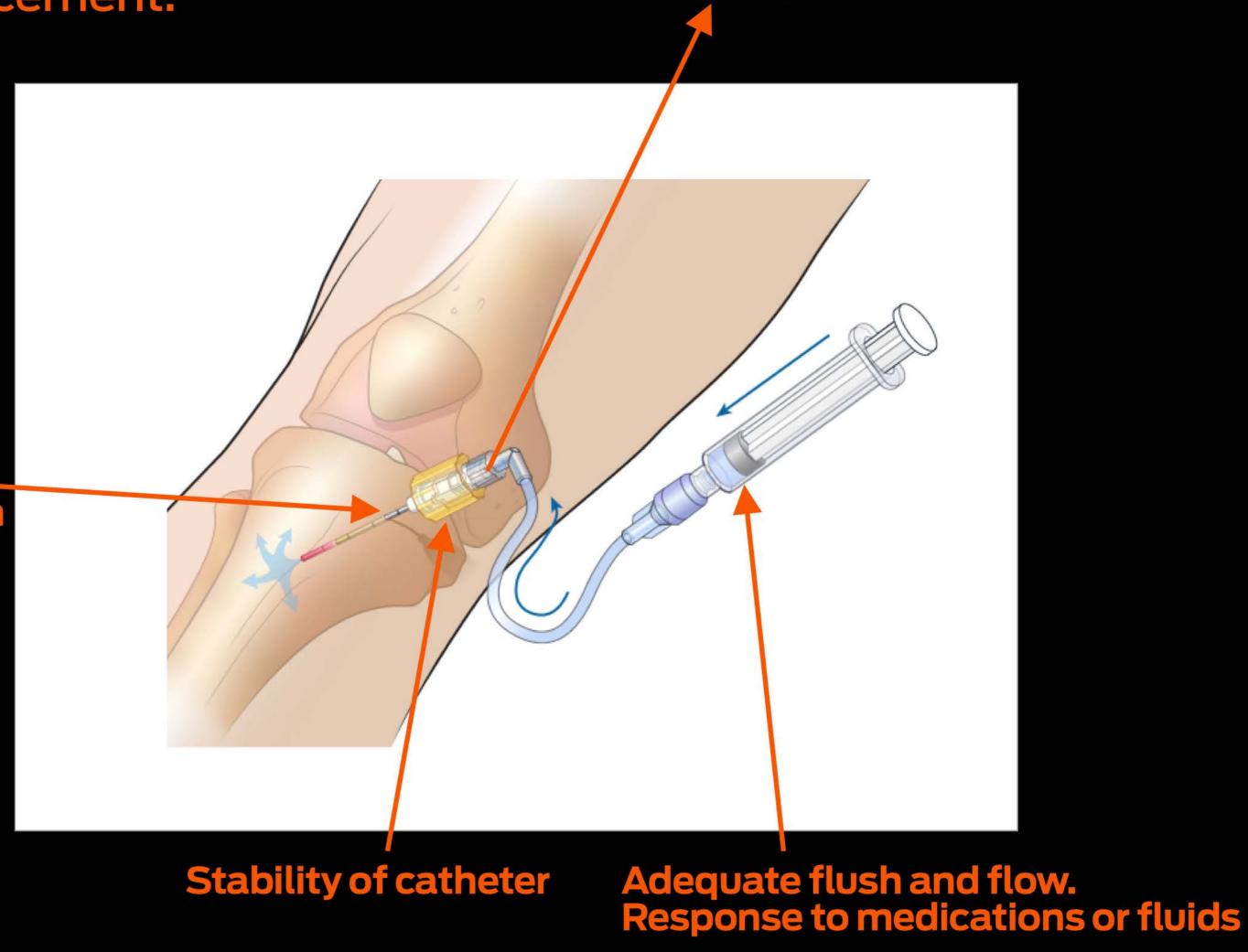
Failure to appropriately flush IO catheter may result in limited or no flow.



Describe indications of successful IO placement.

Confirmation and reconfirmation of catheter placement must routinely include one or more recommended methods.

No extravasation

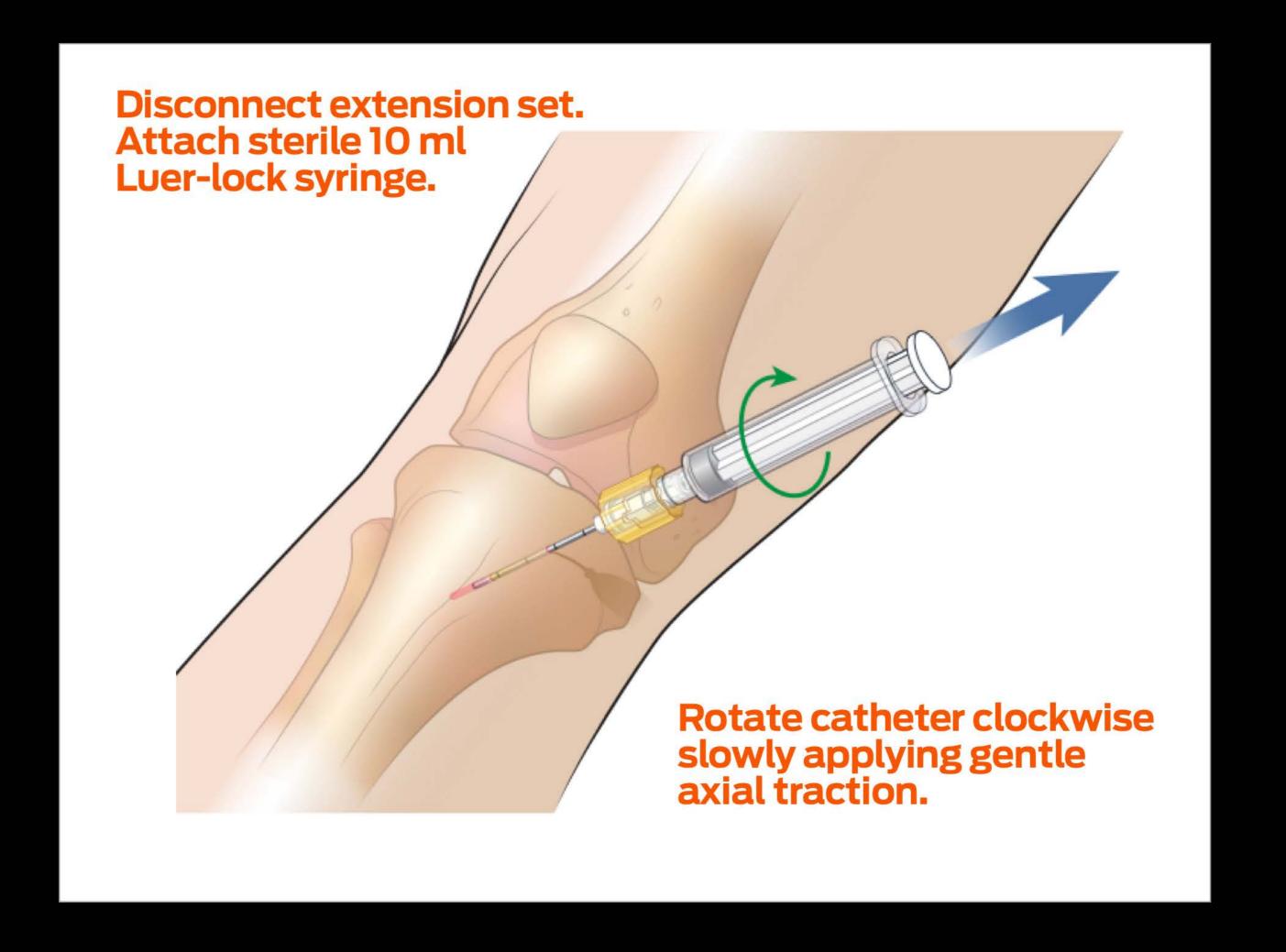


Ability to aspirate blood

Demonstrate method for IO removal.

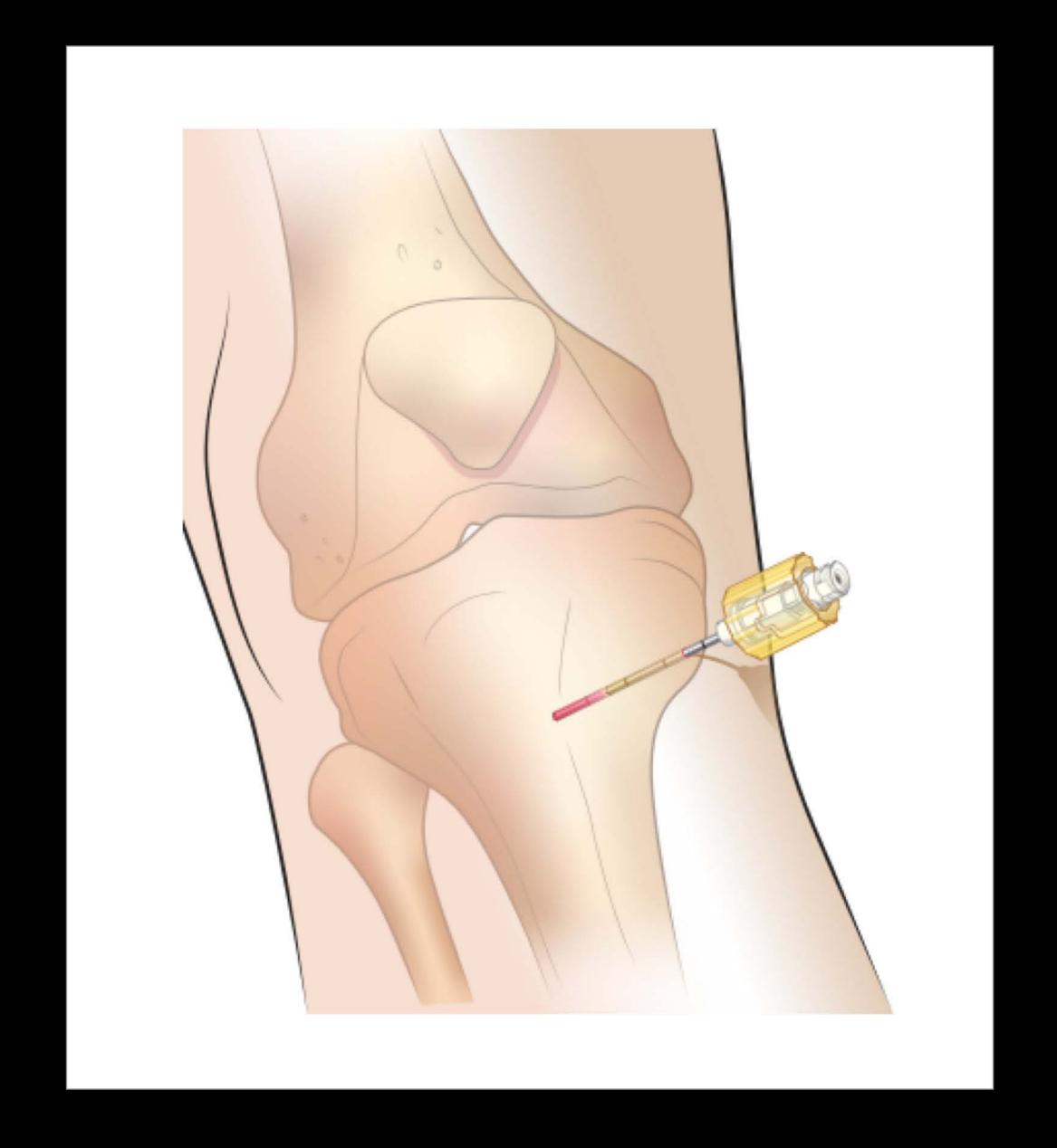
Removal of SAM IO® catheter.

Appropriately dispose of sharps.
Control bleeding with pressure.
Dress site according to protocol.

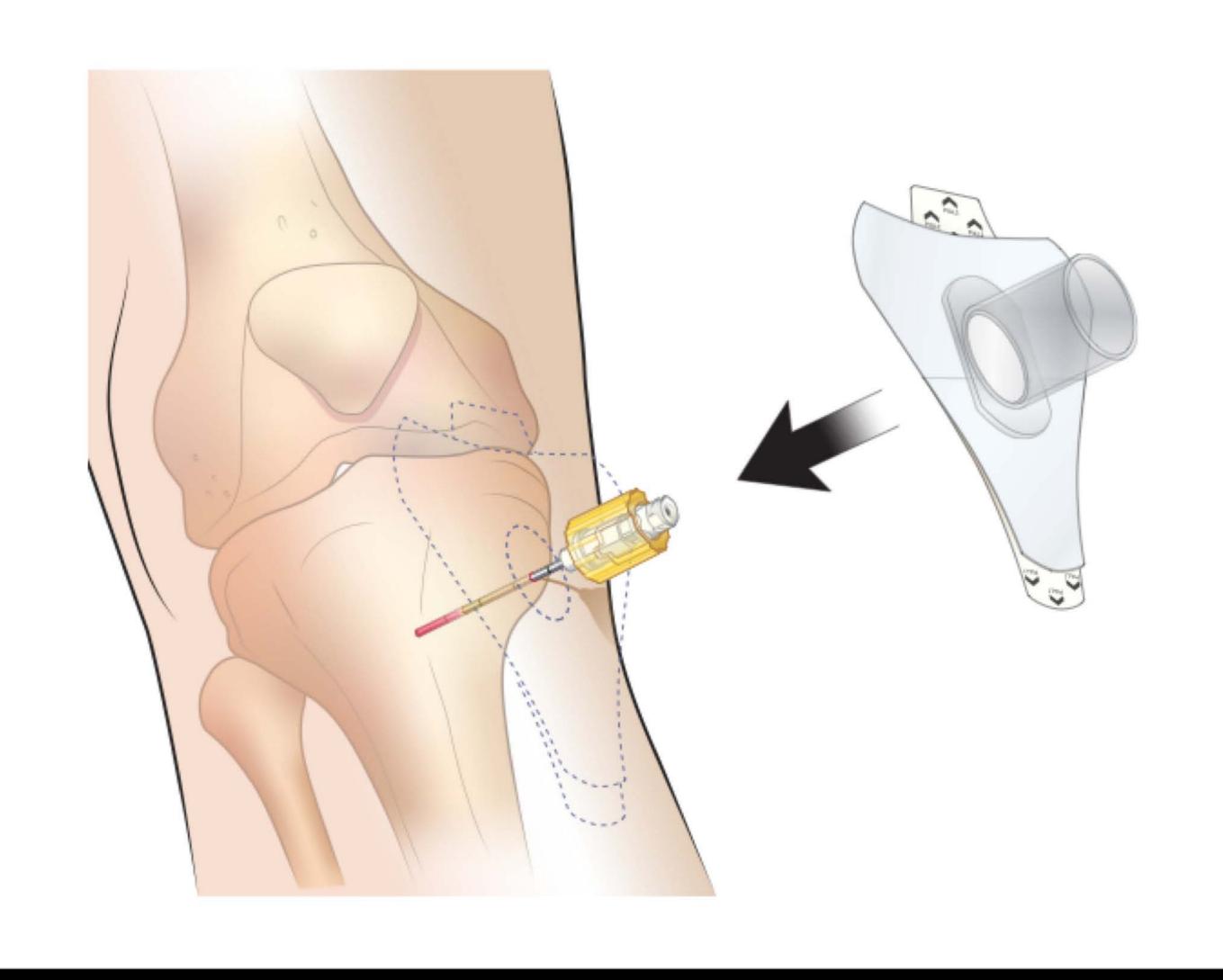


SAMIO Stabilizer

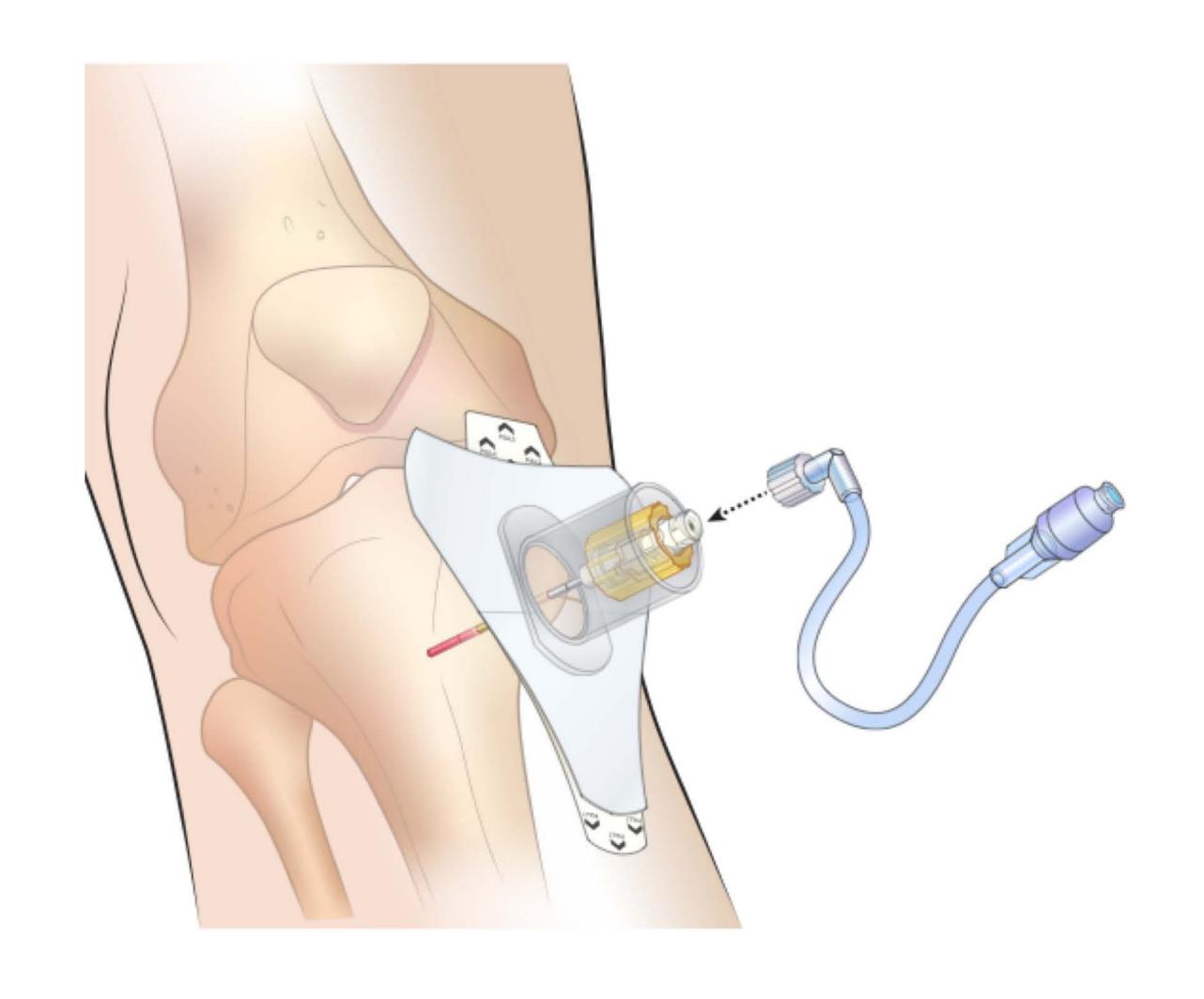
With SAM IO® catheter in position, consider use of SAM® Stabilizer.



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

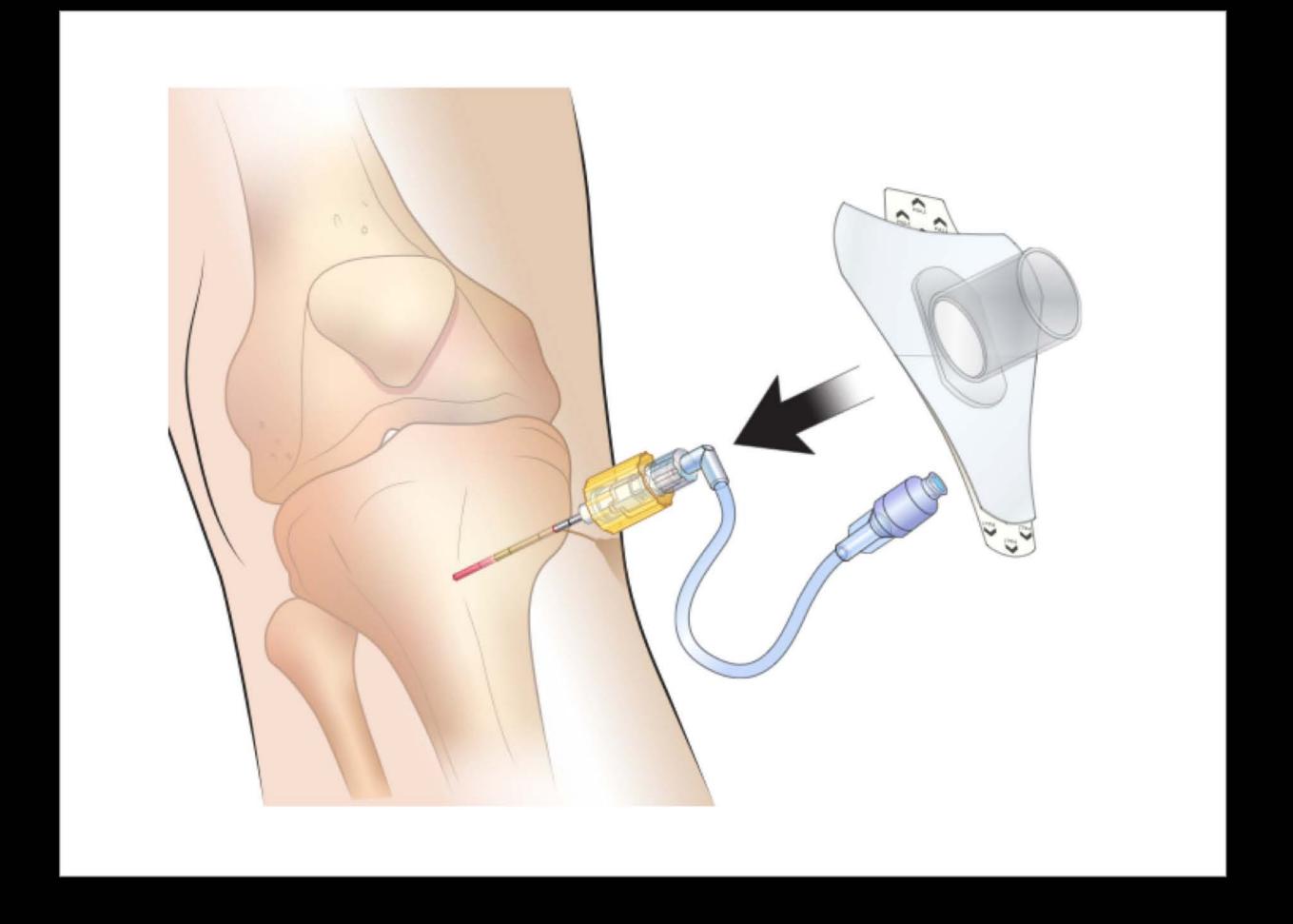


Attach primed extension set to SAM IO® Catheter.
KEY POINT: Extension set design permits single-handed tightening to catheter.

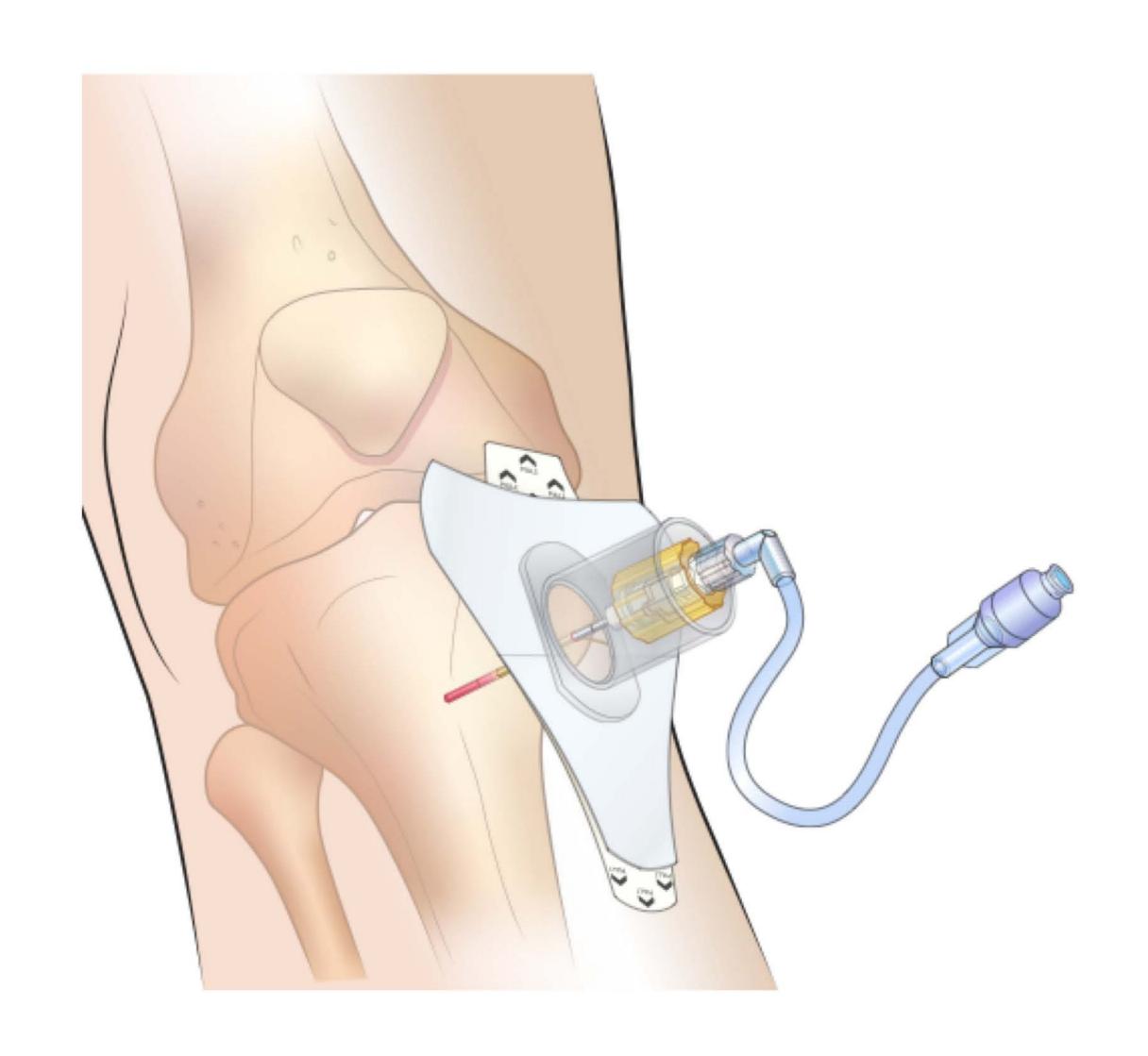


OPTIONAL APPLICATION METHOD

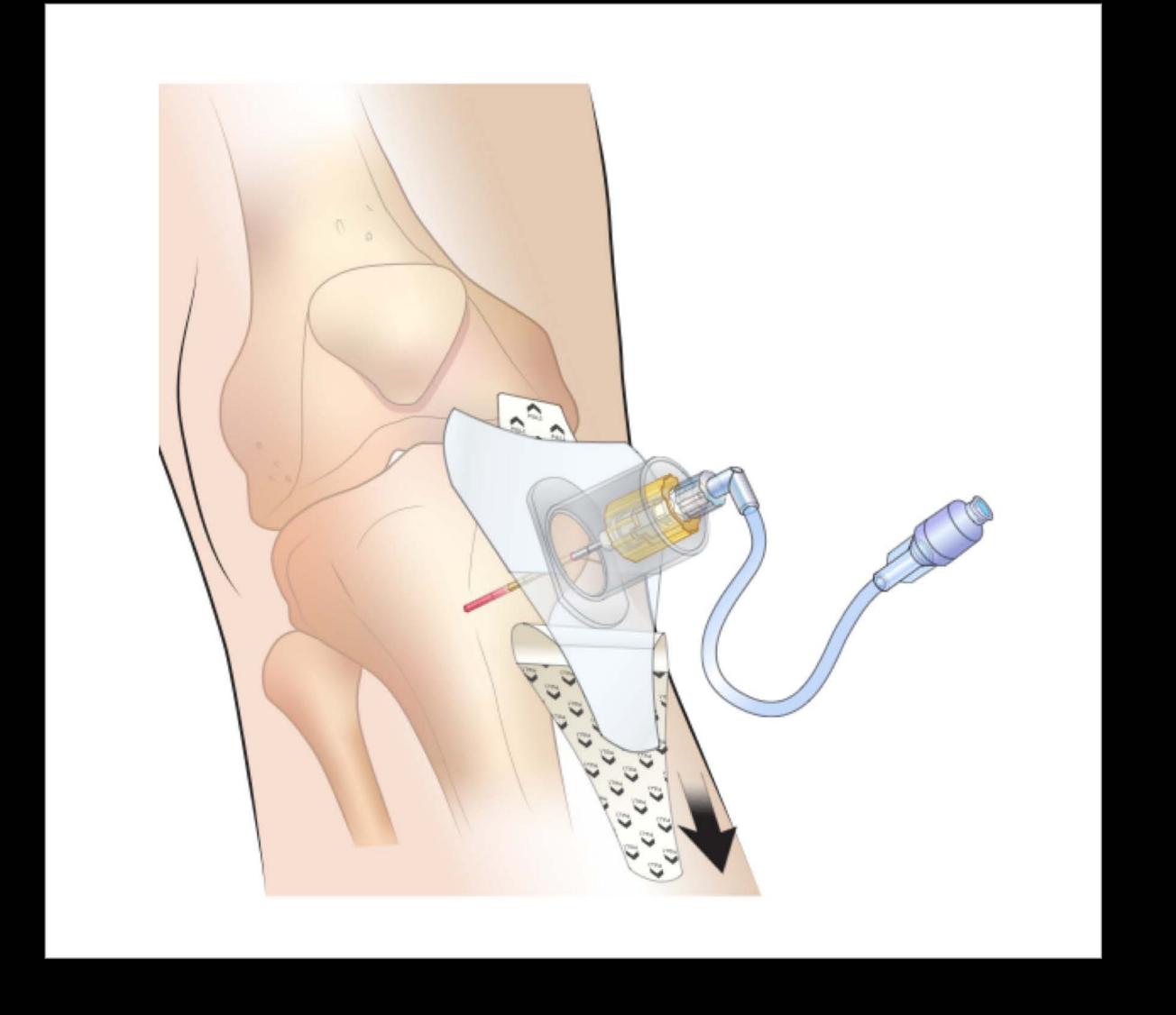
With attached extension set in position, gently feed extension set through stabilizer cylinder. Guide stabilizer over catheter, and against patient skin.



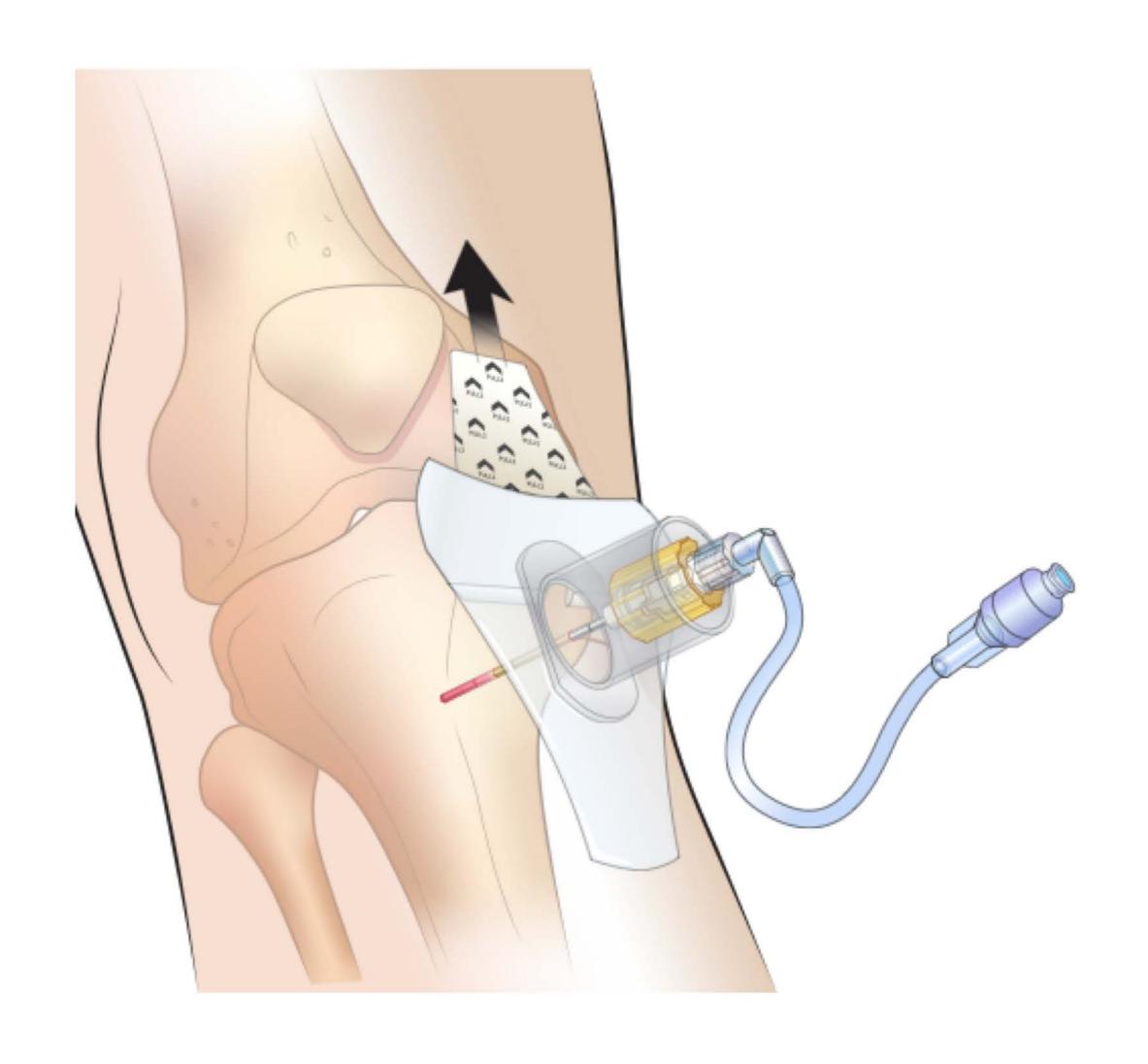
Ensure SAM IO® Catheter is centered within SAM® Stabilizer



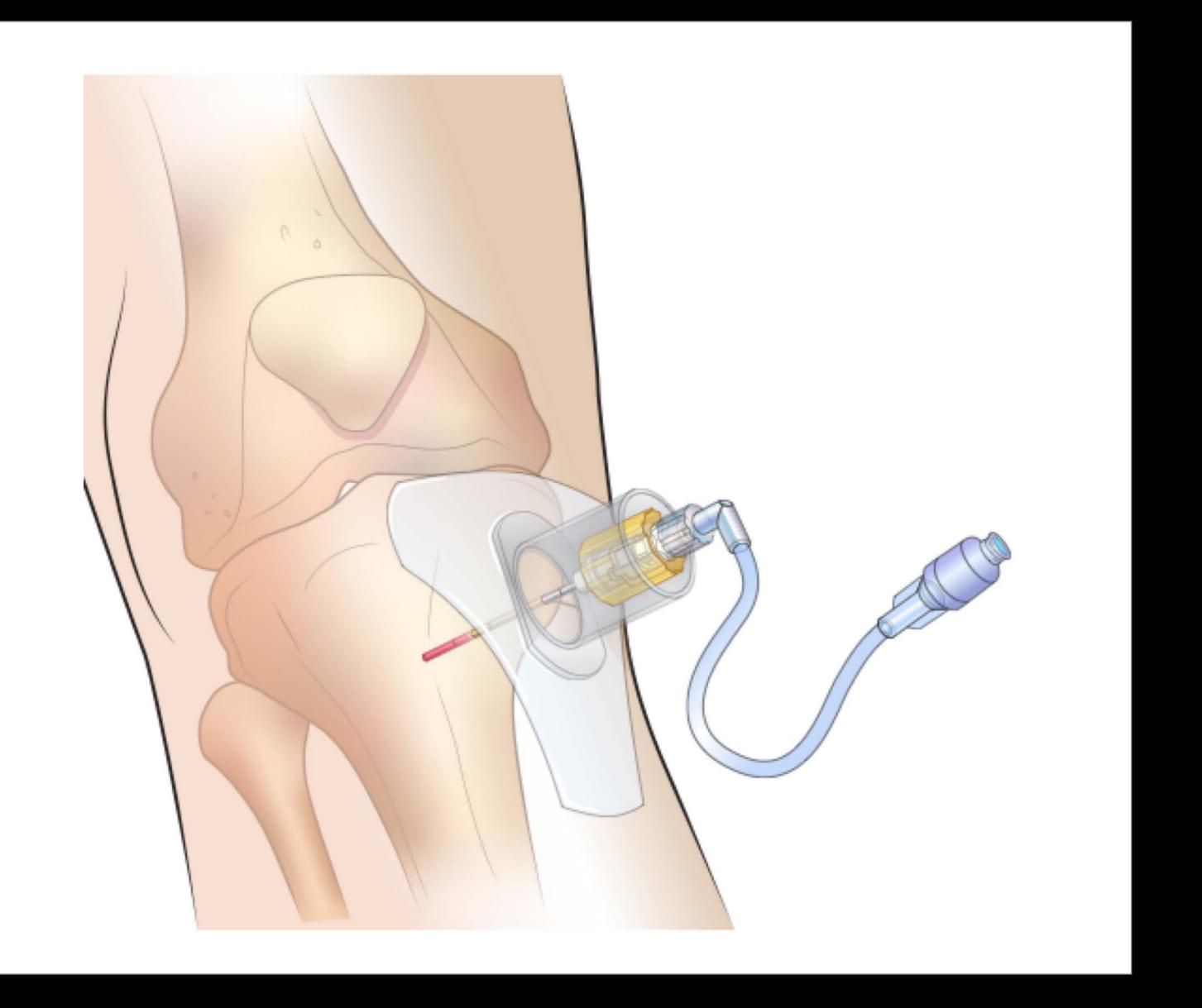
Hold SAM® Stabilizer in position and gently pull Tab 1. By pulling Tab 1 you are removing adhesive backing. This will expose adhesive to patient skin. Gently press exposed adhesive against patient skin.



Hold SAM® 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.



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



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