

A photograph showing two paramedics in blue uniforms with "OREGON PARAMEDIC" patches performing a medical procedure on a patient lying on a rug in a living room. One paramedic is using a SAM IO device on the patient's arm, while the other observes. A woman with white hair is also present, looking on. Medical equipment, including a SAM IO kit and a LIFEPAK, is visible on the floor. The scene is dimly lit, with light coming from large windows in the background.

SAM IO TRAINING

SAM[®]
MEDICAL

SAM[®]
MEDICAL

INDICATIONS FOR USE



INDICATIONS FOR USE

Indications for Use:

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

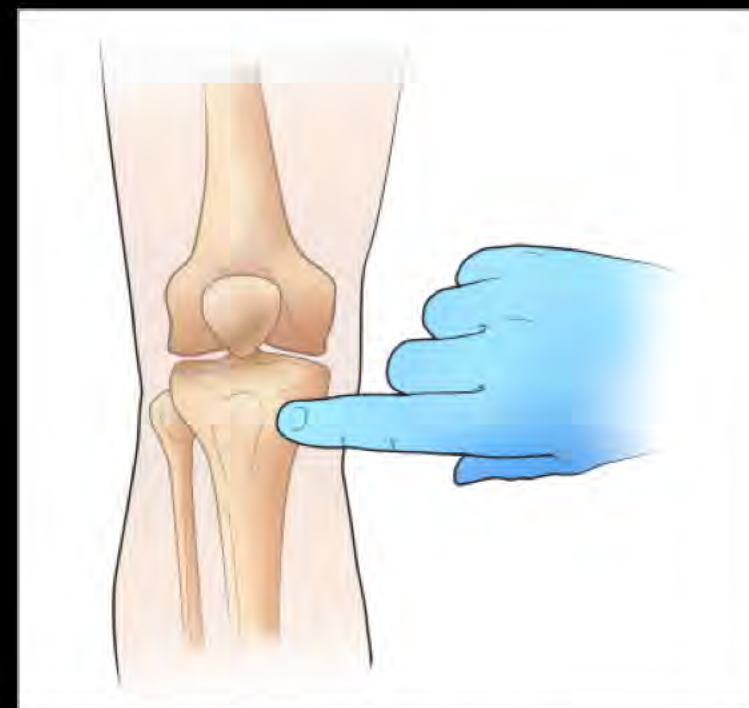
Contraindications:

- 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.

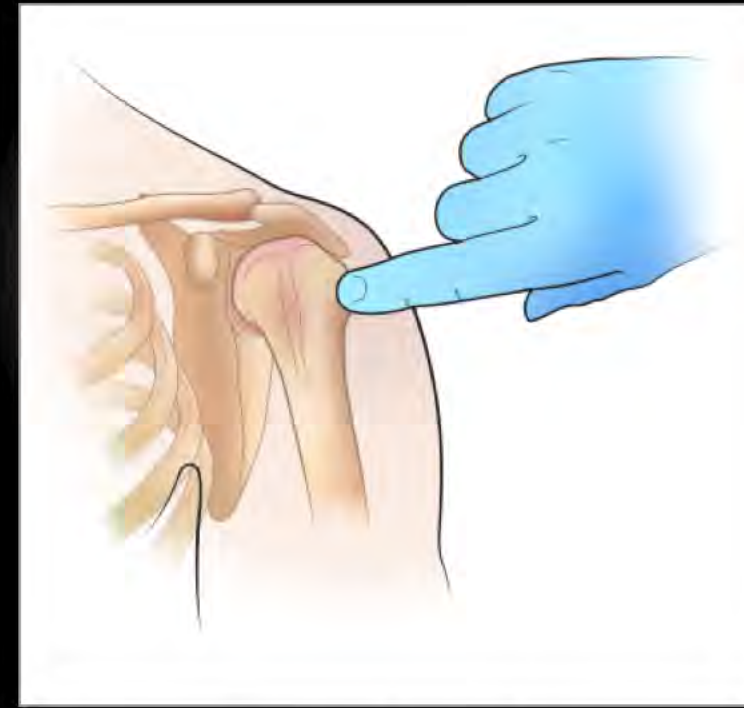
SAM IO APPLICATION SITES

The SAM IO is indicated for use within eight specific application sites (Proximal Tibia, Proximal Humerus, Distal Tibia and Distal Femur - left and right)

ADULT



Proximal Tibia



Proximal Humerus



Distal Tibia



Distal Femur



Proximal Humerus



Distal Tibia



Proximal Tibia

PEDIATRIC



Distal Femur



Proximal Humerus



Distal Tibia



Proximal Tibia

A photograph of an elderly woman with short white hair, wearing a blue denim shirt, sitting on the floor and holding the hands of an elderly man with white hair, wearing a blue and white plaid shirt. The man is lying on his side with his head resting on his hands. The woman is looking down at his hands with a concerned expression. The background is a warm, wooden wall. The text "IO BACKGROUND" is overlaid in the center in a bold, white, sans-serif font.

IO BACKGROUND

IO UTILIZATION

Intraosseous (IO) access is utilized in critical, emergent, and urgent situations where intravenous (IV) access cannot be obtained effectively and efficiently. This is commonly due to:

- Trauma
- Difficult or absent IV access opportunity
- Patient IV access will take greater than 2 attempts or greater than 90 seconds to achieve (based on protocol/policy)
- Cardiac arrest
- Poor general health
- Drug abuse

Common Standard of Care: IO access should be considered in any critical situation requiring the administration of fluids and medications where vascular access cannot be rapidly obtained.

IO EFFECTIVENESS

Studies have shown the effectiveness of IO in emergent, urgent, or medically necessary situations.

- In a retrospective analysis, Ross et al compared 2,601 cases of intraosseous (IO) usage with 55 cases of peripheral intravenous (PIV) usage in out-of-hospital cardiac arrest (OHCA) patients. They concluded, “In the setting of OHCA, the time to administer the first dose of epinephrine was faster in the IO access group when compared to PIV access group. The prehospital use of IO vascular access for time-dependent medical conditions is recommended.”

Ross EM, Mapp J, Kharod CU. Time to epinephrine in out of hospital cardiac arrest: A retrospective analysis of intraosseous versus intravenous access. *Ann Emerg Med* 2016;68(4s):S61.

- In a systematic review of 84 full-text articles, Petitpas et al found 49 that were useful for answering the following question: “when, how, and for which population should an IO infusion be used in adults?” The authors results concluded: “IO infusion should be implemented in all critical situations when peripheral venous access is not easily obtainable. Contraindications are few and complications are uncommon, most of the time bound to prolonged use. The IO infusion allows for blood sampling and administration of virtually all types of fluids and medications including vasopressors, with a bioavailability close to the intravenous route. Unfortunately, IO infusion remains underused in adults even though learning the technique is rapid and easy.”

F. Petitpas , J. Guenezan , T. Vendeuvre , M. Scepi , D. Oriot , O. Mirmoz . Use of intra osseous access in adults: a systematic review. *Crit Care*. 2016; 20: 102. 10.1186/s13054-016-1277-6

SAM IO

SAM IO Needle Set

TRAUMA



SAM IO OVERVIEW

SAM IO™ is a manually operated intraosseous access system. Catheter placement is achieved by continuously actuating (repeatedly compressing) driver's trigger assembly while gently guiding needle assembly, available in 15 mm, 25 mm, and 45 mm lengths, 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.

SAM IO DRIVER



SAM IO DRIVER

**Multi-use – tested to
hundreds of actuations**

Battery-free design

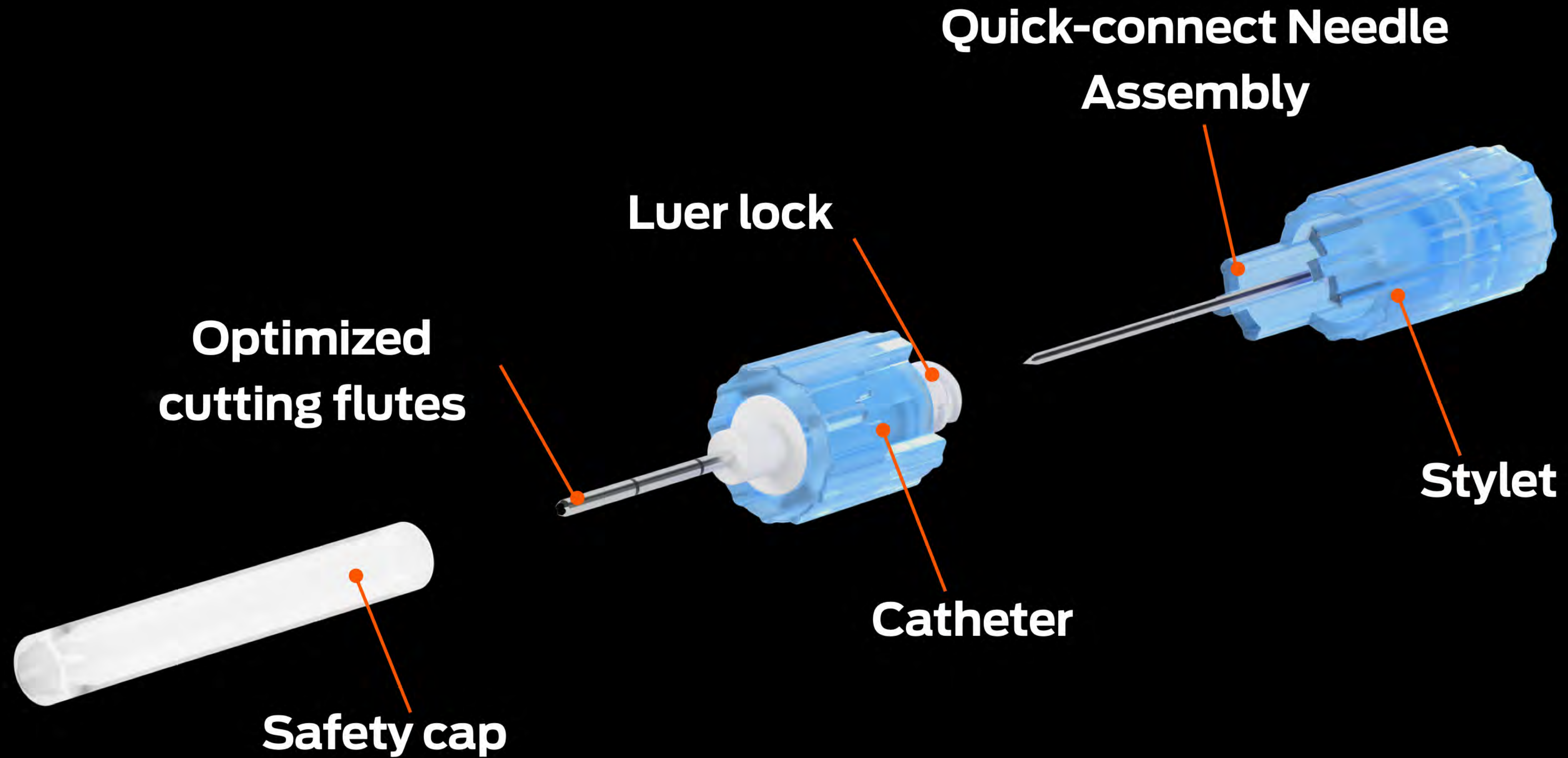
**Polycarbonate materials –
built with hard use and
harsh environments in mind**

Size: (5.5"(L) x 1"(W) x 4.25"(H)

Weight: (2.5oz)



SAM IO NEEDLE ASSEMBLY



SAM IO NEEDLES

Available in 1-packs and
5-packs

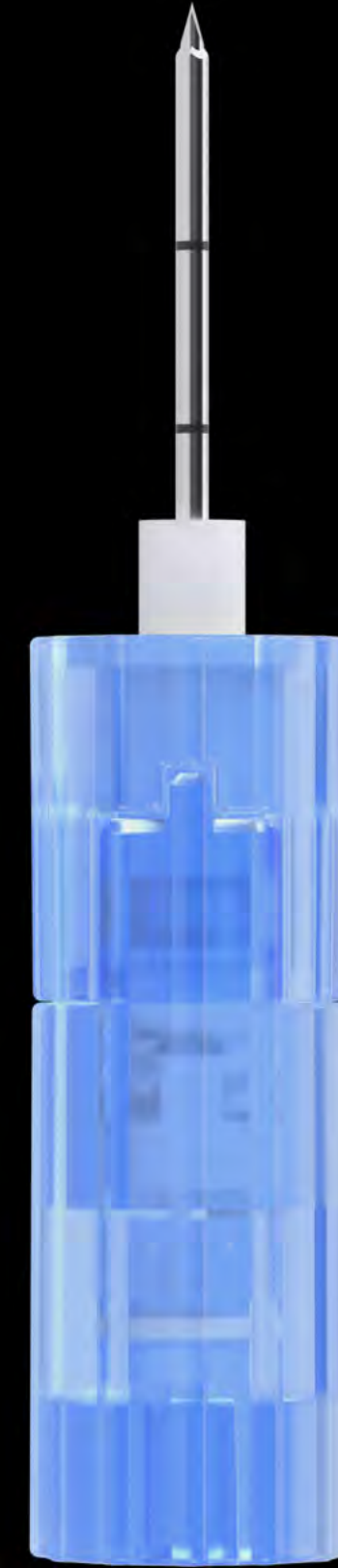
Three lengths

Intuitive color
identification

Depth indication



15 mm Needle



25 mm Needle

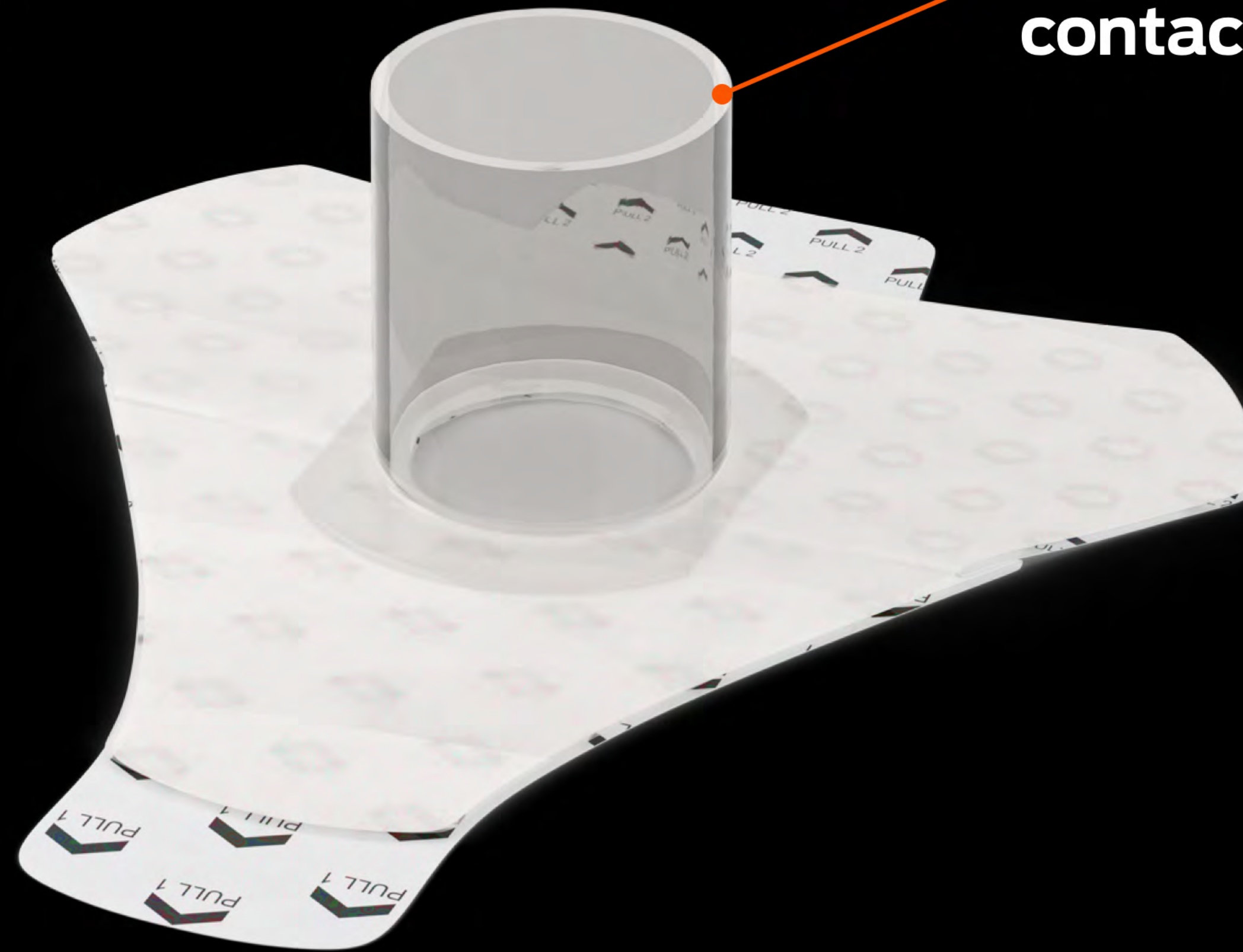


45 mm Needle

SAM IO STABILIZER

Available in 1-packs and
5-packs

Cylinder design - no needle
contact



SAM IO ACCESSORIES

Accommodates
alternative
IO needles



Adaptor

Sharps
containment

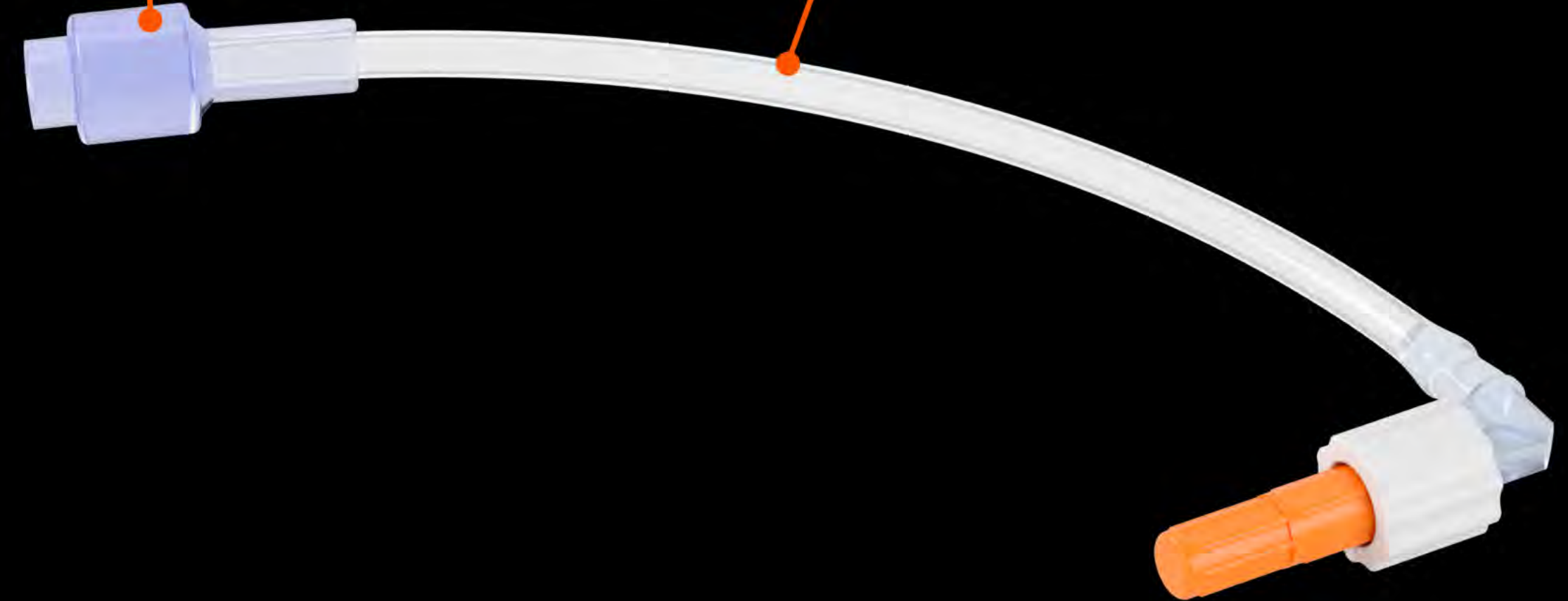


NeedleVISE®

Needleless Port



Flexible
extension tubing



Extension Tube



WHY SAM IO?

SAM IO DRIVER

The SAM IO utilizes a multi-use and manually powered driver for efficient and controlled IO access. The driver is cleanable and tested to hundreds of actuations, while the manual operation eliminates battery-related failure and reduces the weight of the driver.

The driver functions through a passive ratcheting mechanism which causes the needle to only rotate clockwise when resistance is encountered. Through actuation of the driver handle, the user provides controlled insertion of the IO needle with a tactile feel of cortical penetration.



SAM IO NEEDLES

The 15 gauge SAM IO Needles come in **15 mm**, **25 mm**, and **45 mm** lengths to accommodate multiple application sites and a broad range of patient demographics.

The colors and depth indicators adhere to industry standards for ease of adoption, and the stylet and catheter are connected through a simple snap-fit design.

SAM IO Needles utilize a 5-point grind which is intended to aid in insertion with the SAM IO Driver, or through manual insertion by hand.



15 mm Needle



25 mm Needle



45 mm Needle

SAM IO ACCESSORIES

Each sterile-packed SAM IO Needle includes an Extension Tube to aid in fluid introduction, and a NeedleVISE® for sharps containment.

The SAM IO Stabilizer features a cylinder design which helps shield the IO needle from dislodgement. The cylinder does not come into contact with the needle itself, potentially offering additional protection.

The SAM IO Adaptor is designed to accommodate alternative IO needle designs with the SAM IO Driver.



Stabilizer



Adaptor



Extension Tube



NeedleVISE®

SAM IO INSTRUCTIONS FOR USE

DETERMINE APPLICATION SITE AND NEEDLE LENGTH

ADULT



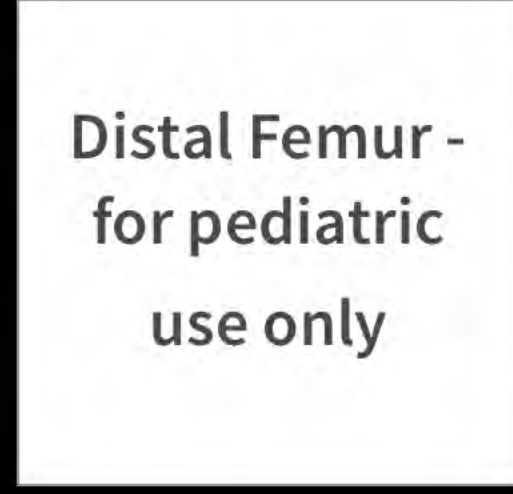
Proximal
Humerus



Proximal
Tibia



Distal
Tibia



Distal Femur -
for pediatric
use only

PEDIATRIC



Proximal
Humerus



Proximal
Tibia



Distal
Tibia



Distal
Femur



15 mm Needle
Indicated for
patients
weighing
3 - 39 kg*



25 mm Needle
Indicated for
patients
weighing 3 kg
or over*



45 mm Needle
Indicated for
patients
weighing 40 kg
or over*

When placing needle, ensure that ≥ 5 mm of catheter (at least first black line on proximal catheter) is visible above the skin

*General weight ranges, see Instructions for Use for more information

STEP 1

Clean insertion site per institutional protocol or policy (fig. 1)



(fig. 1)

STEP 2

PREPARE SUPPLIES:

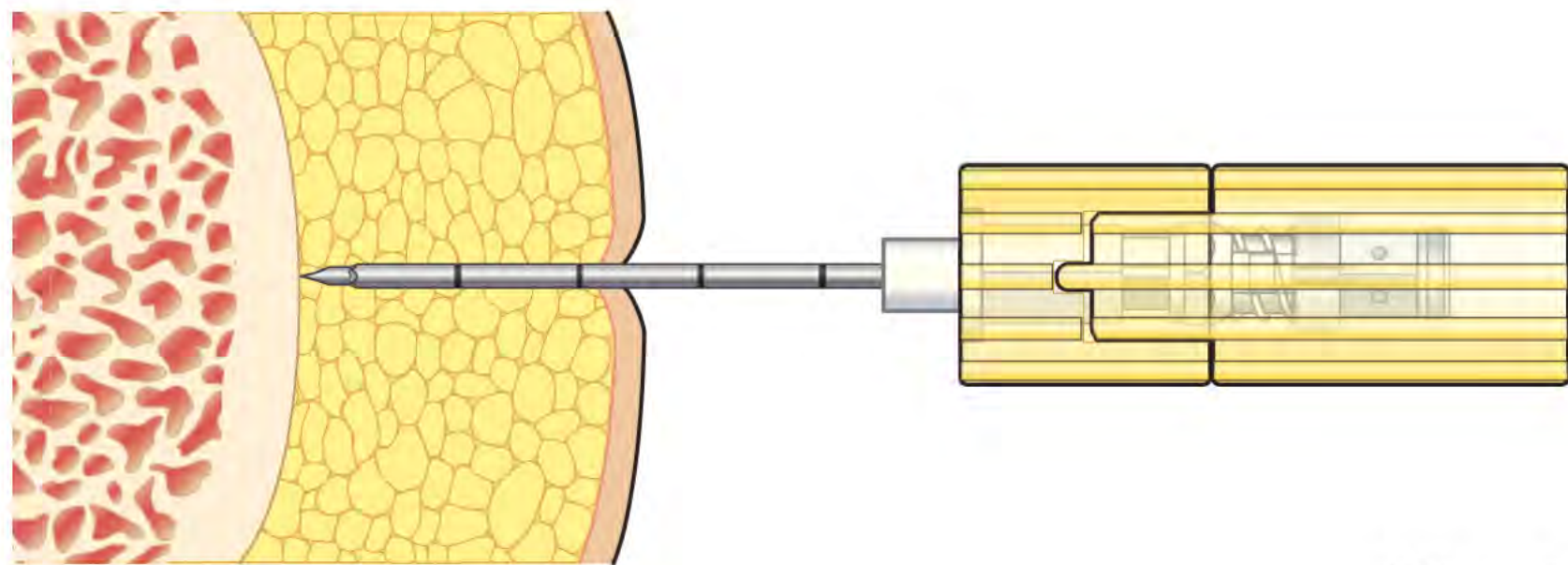
- Prime infusion set.
- Attach needle assembly to driver.
- Remove safety cap from needle assembly.

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

IMPORTANT: Control patient movement prior to and during procedure.

STEP 3

Insert needle assembly through skin and adipose tissue. Needle assembly tip should come to rest against targeted periosteum / bone (fig. 2)



(fig. 2)

STEP 4

Ensure that ≥ 5 mm of catheter (at least first black line on proximal catheter) is visible above the skin (fig 2).

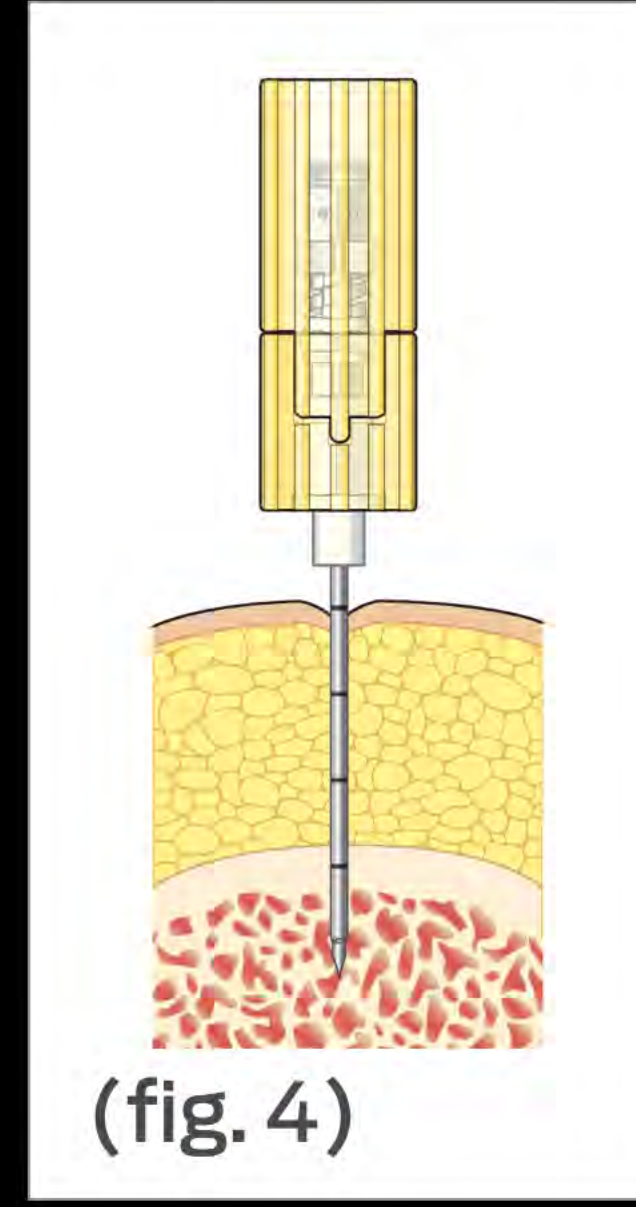
IMPORTANT: Most accurate determinant of needle assembly length related to safe intraosseous access are black depth indicators on catheter.

- 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.

STEP 5

Continuously actuate (repeatedly compress) driver's trigger assembly, while applying gentle, steady downward insertion pressure to achieve controlled entry (fig. 3 & 4).

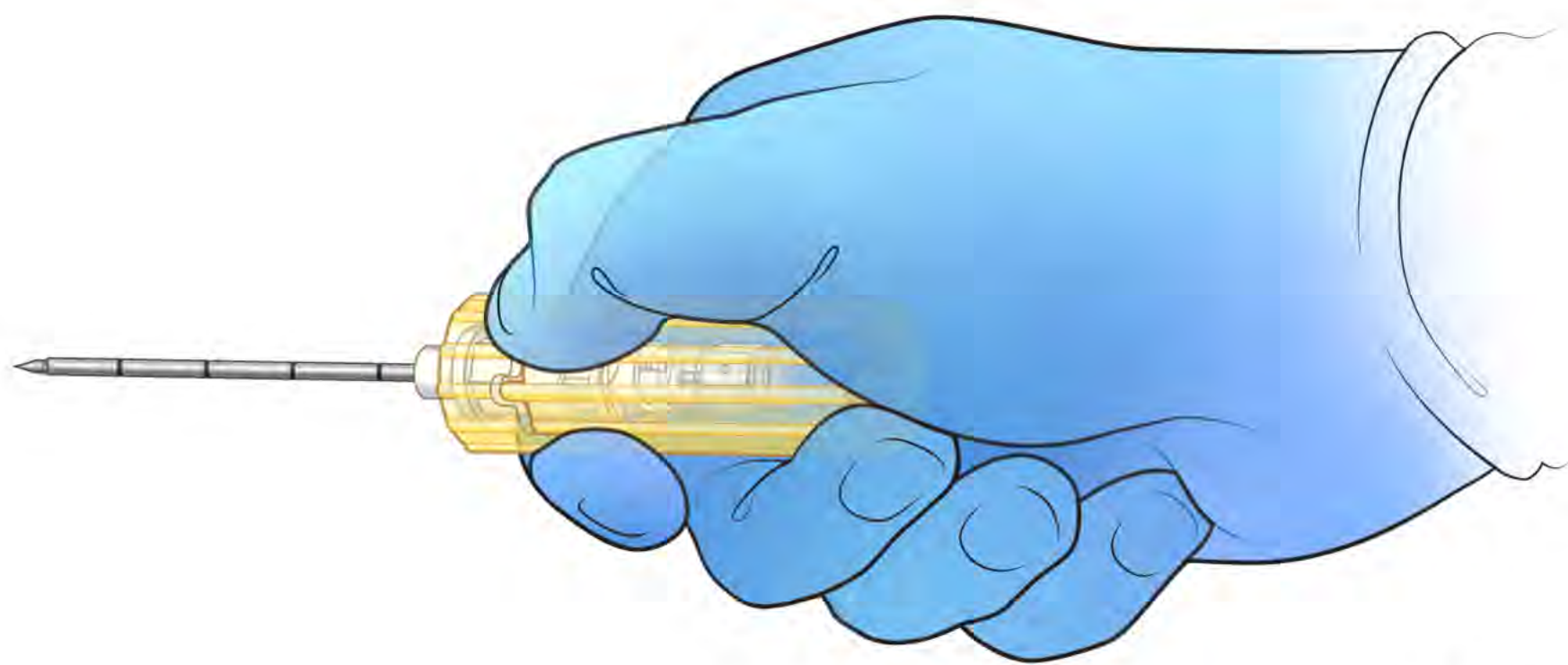


IMPORTANT: DO NOT USE EXCESSIVE FORCE. Use minimal (gentle) steady downward insertion pressure. Allow needle assembly tip rotation to penetrate compact bone. The mechanical rotation of the needle by handle actuation and the cutting edge of the needle should be the PRIMARY mechanisms to penetrate bone, 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. 4).

STEP 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. 5).



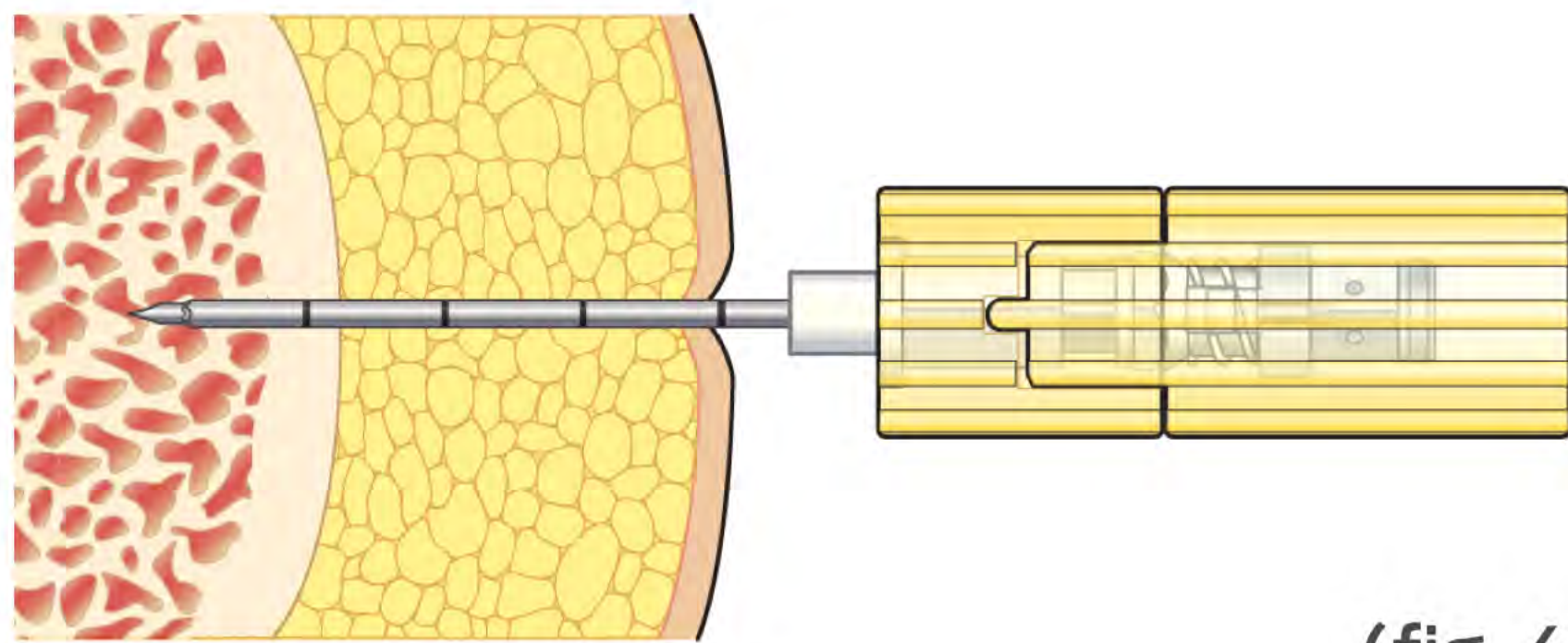
(fig. 5)

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 (fig. 4).

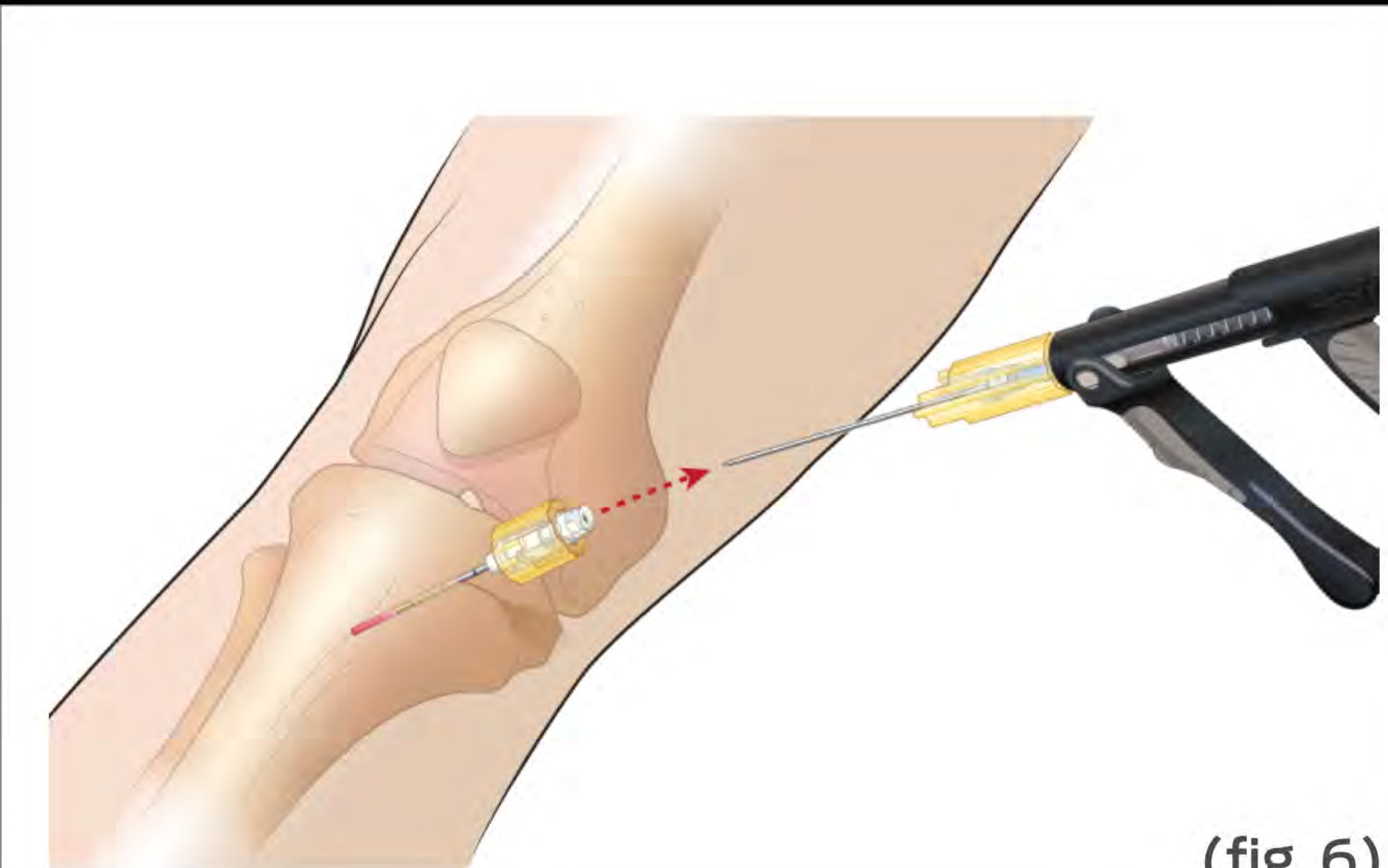
NOTE: It is rarely necessary, nor advised, to have catheter hub flush against skin.



(fig. 4)

STEP 7

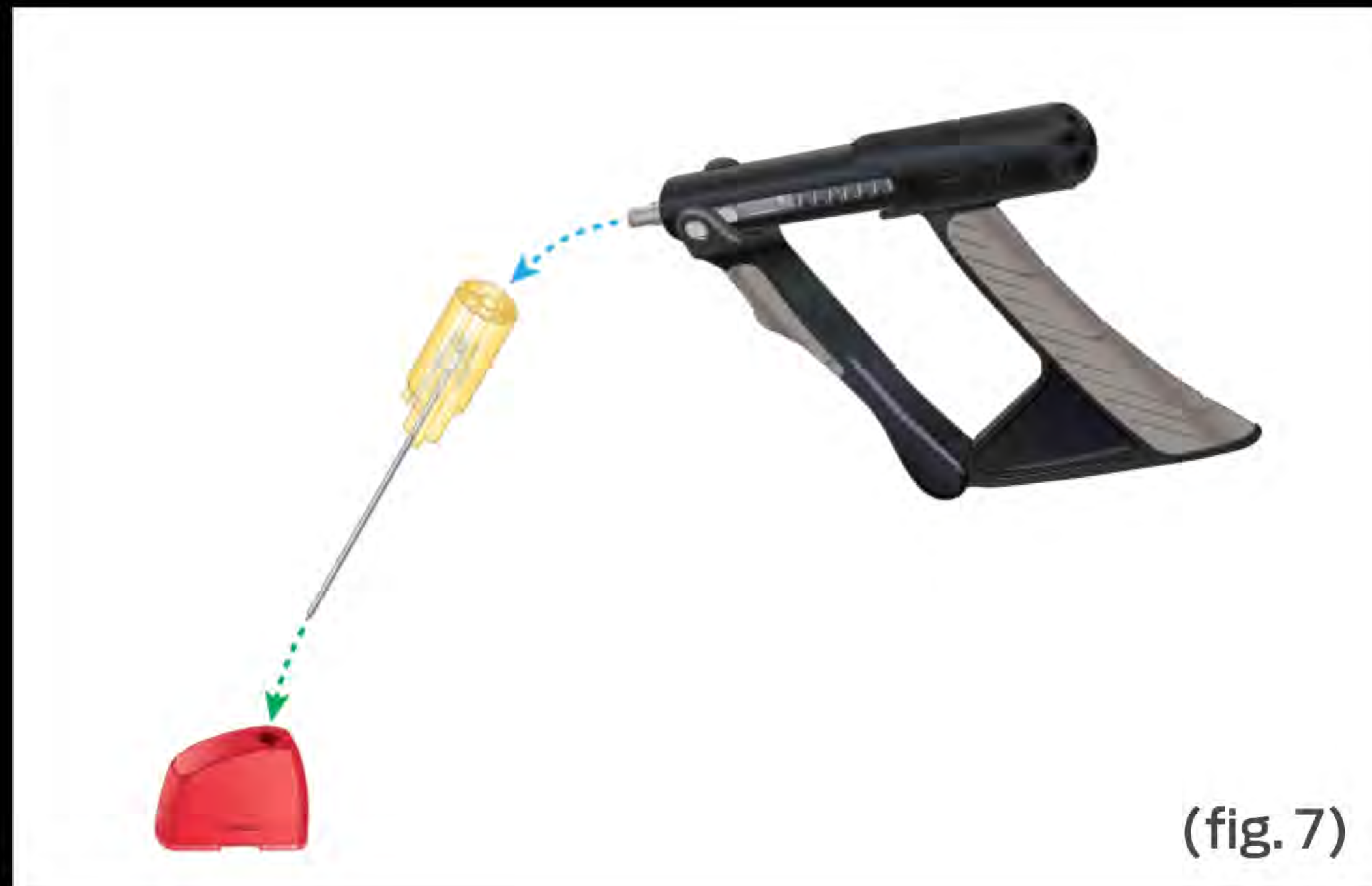
Remove stylet by stabilizing needle assembly hub while retracting (lifting off) and disconnecting driver. Stylet will remain attached to driver (fig. 6).



(fig. 6)

STEP 8

Remove stylet by stabilizing needle assembly hub while retracting (lifting off) and disconnecting driver. Stylet will remain attached to driver (fig. 7).



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®.

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 (fig. 8).

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:

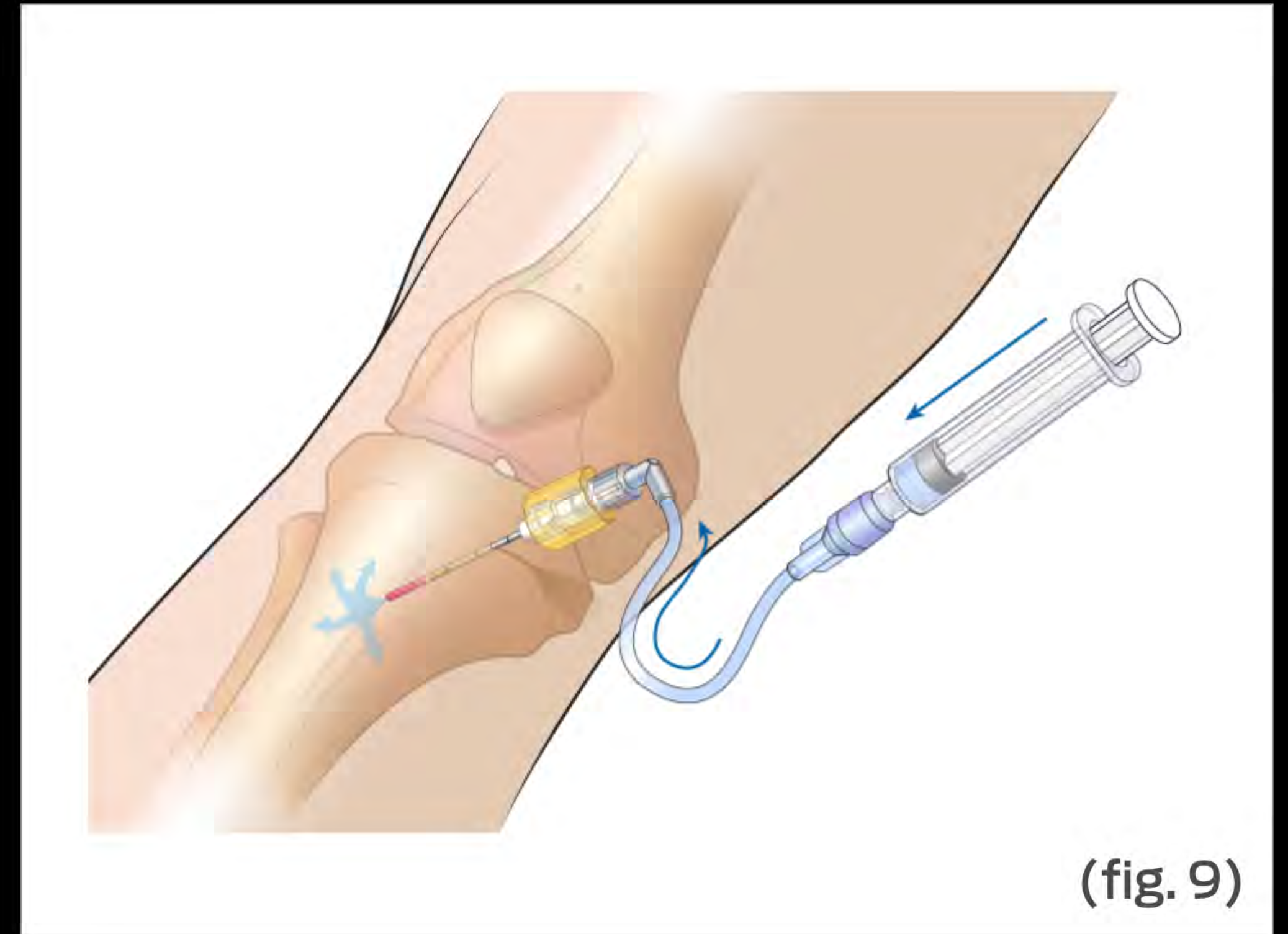
- Identified blood at stylet tip.
- Noted stability of catheter in bone.
- Noted ability to aspirate blood from catheter.
- Noted ability to flush catheter without extravasation.
- Appreciation of adequate flow rate.
- Noted patient response to medication or fluid.

STEP 14

Flush SAM IO™ with normal saline as directed by protocol or standard. Repeat flush as needed (fig. 9).

- 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.

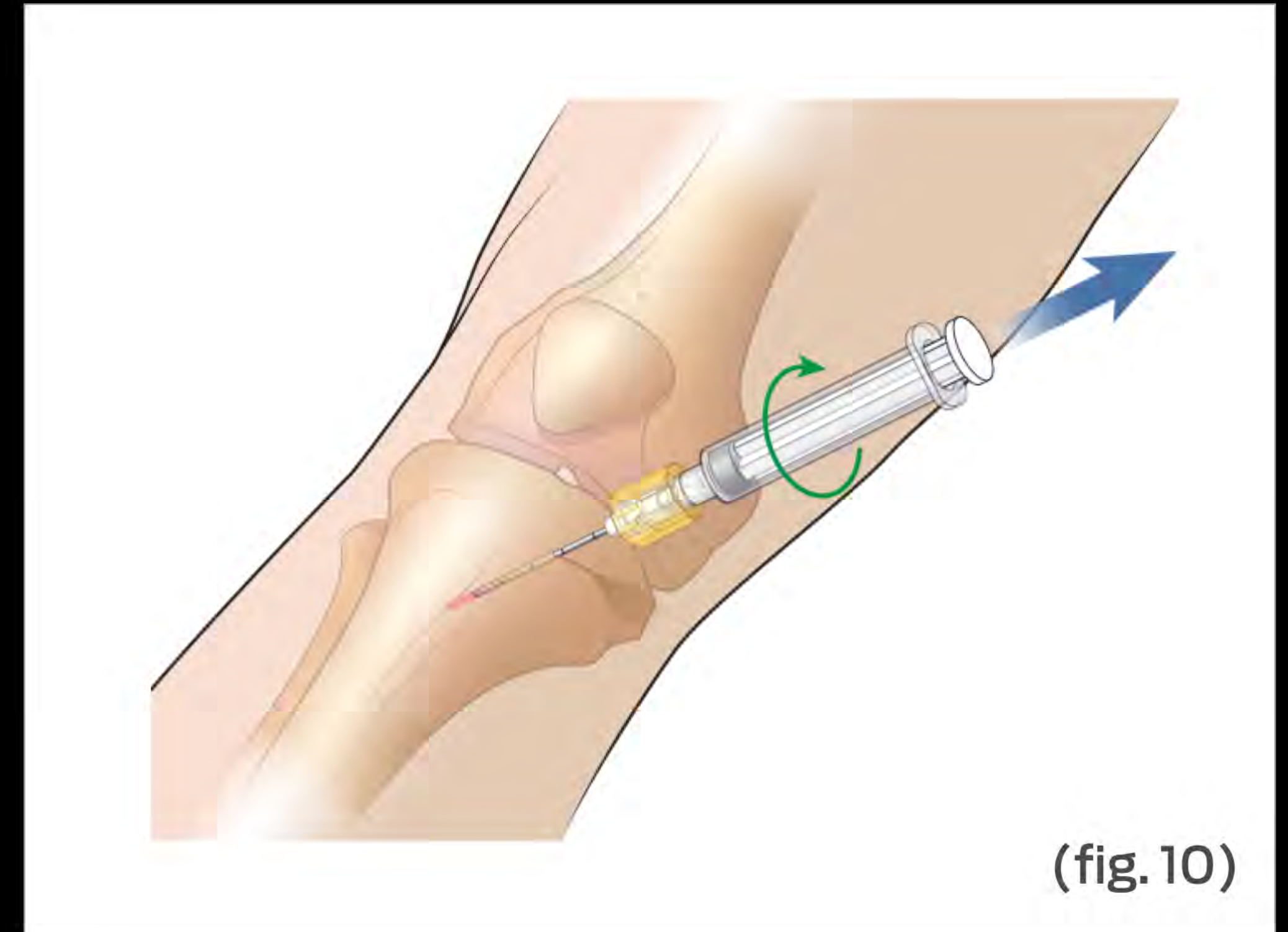


(fig. 9)

STEP 15

To remove SAM IO™ catheter from patient (fig. 10):

- 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.



SUMMARY



SAM IO SUMMARY

- Multi-use manually operated driver
- 15 mm, 25 mm, and 45 mm needles
- Compact and lightweight
- Chamber-style stabilizer reduces accidental dislodgement of IO catheter
- Accessories to enhance IO insertion and procedural success



THANK YOU

#ENGINEEREDFORSURVIVAL

sammedical.com