

INSIGHTRA
MEDICAL
A MUNDOMEDIS GROUP COMPANY

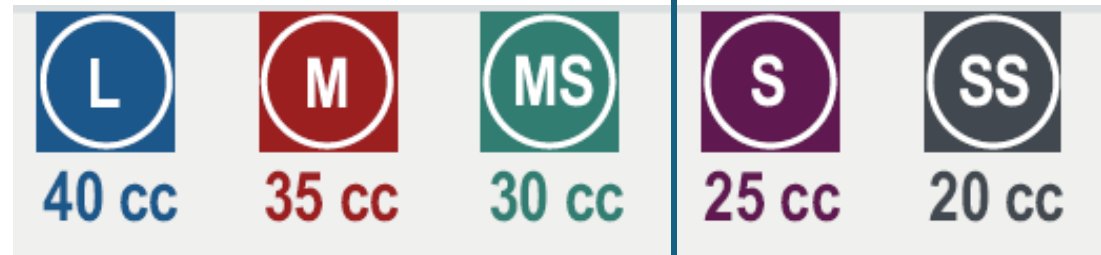
Your Intra-Aortic Balloon Catheter Specialists

THE INSIGHTRA ULTRA IAB 7Fr CATHETER KIT

OUR QUALITY

- Each catheter undergoes 50,000 inflation cycle testing before shipped
- The only IAB Catheter with 5 years shelf life
- 8Fr performance in a 7Fr catheter
- Compatible with all common Datascope and Arrow consoles – kit comes with adaptors
- No recalls since product launch. Global complaint rate below 0.2%

ULTRA 7FR IAB CATHETER PORTFOLIO



Only produced on special request



Insightra Ultra IAB 7Fr Catheter Kit Intro



Main Tray



Accessory Tray

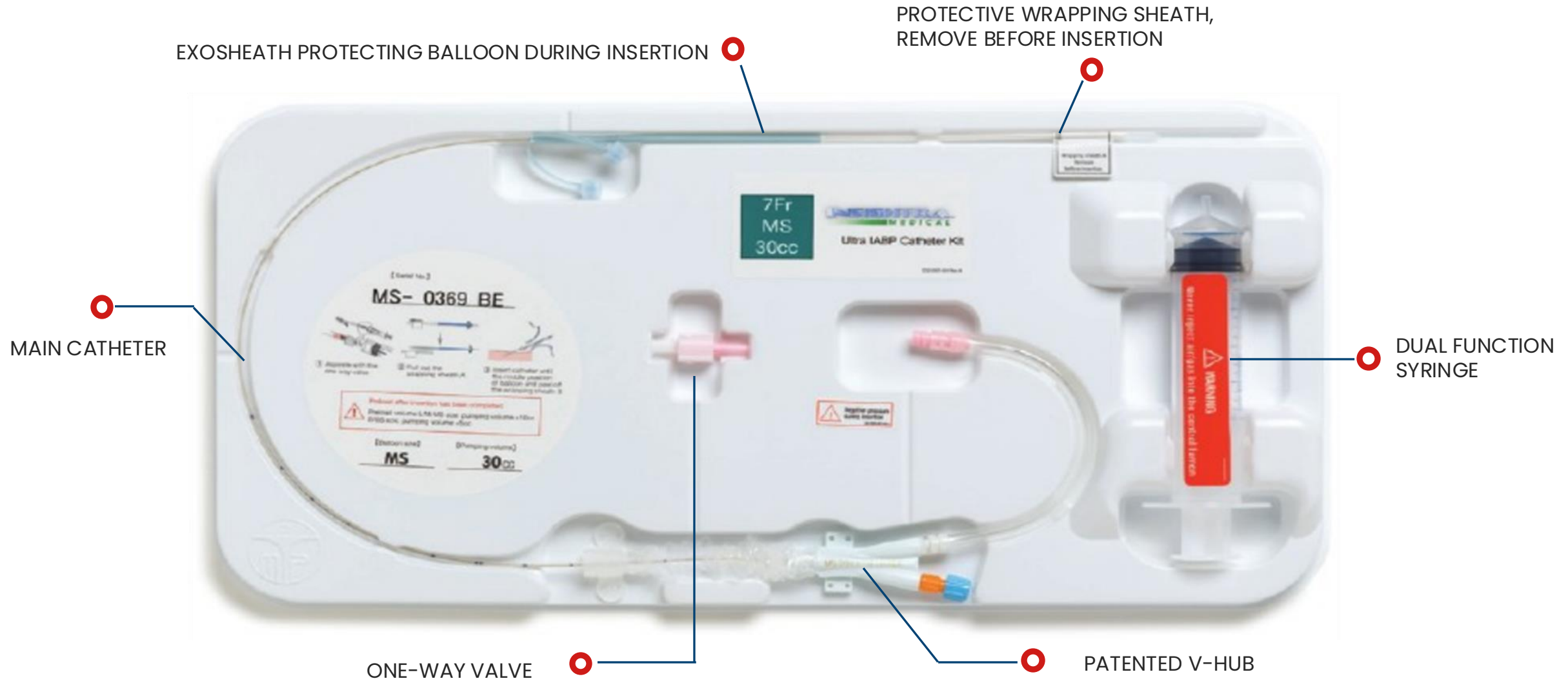


Arrow
Adaptor



Datascope
Adaptor

MAIN TRAY



INSIGHTRA'S BALLOON PROTECTION SHEATHS



PROTECTIVE WRAPPING SHEATH

Our IAB catheter offers a 5-year shelf life, unlike competitors' 3-year limit, due to their hydrophilic coatings, which dry out.

We use a proprietary polyurethane material and a specialized balloon folding technique, involving precise fold alignment and compactness, that ensures minimal resistance during insertion.

This technique, combined with our manufacturing precision, eliminates the need for a hydrophilic coating.

The protective wrapping sheath preserves the balloon's integrity during shelf life.



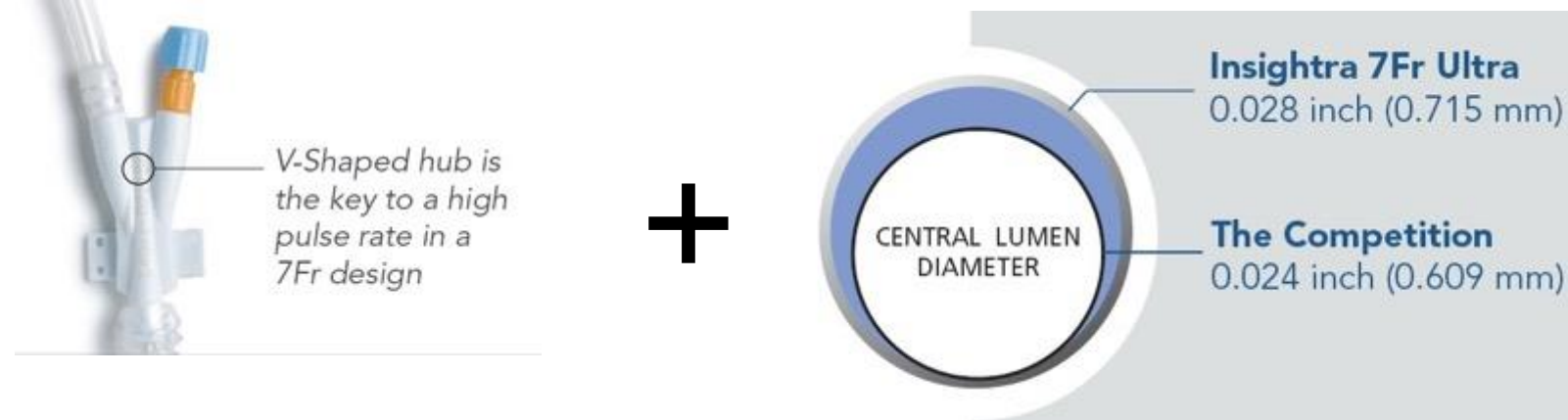
EXOSHEATH

- The Exosheath, a peel-away sheath introducer **removed during insertion**, provides stability and protection for the IAB catheter and the balloon
- IAB catheters are generally prone to kinking
- Insigntra uniquely offers this protective tool, reducing kinking risk and facilitating easier maneuvering of the Insigntra IAB catheter into the insertion site



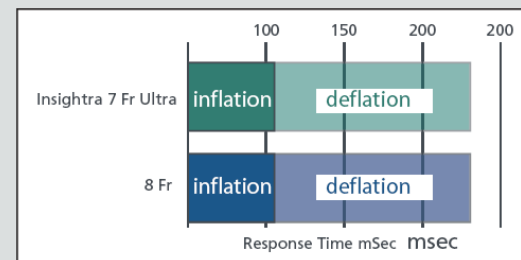
PATENTED V-HUB LARGER CENTRAL LUMEN

- Patent protected V-Hub technology allows significantly improved gas flow over Y-shaped hubs of competition



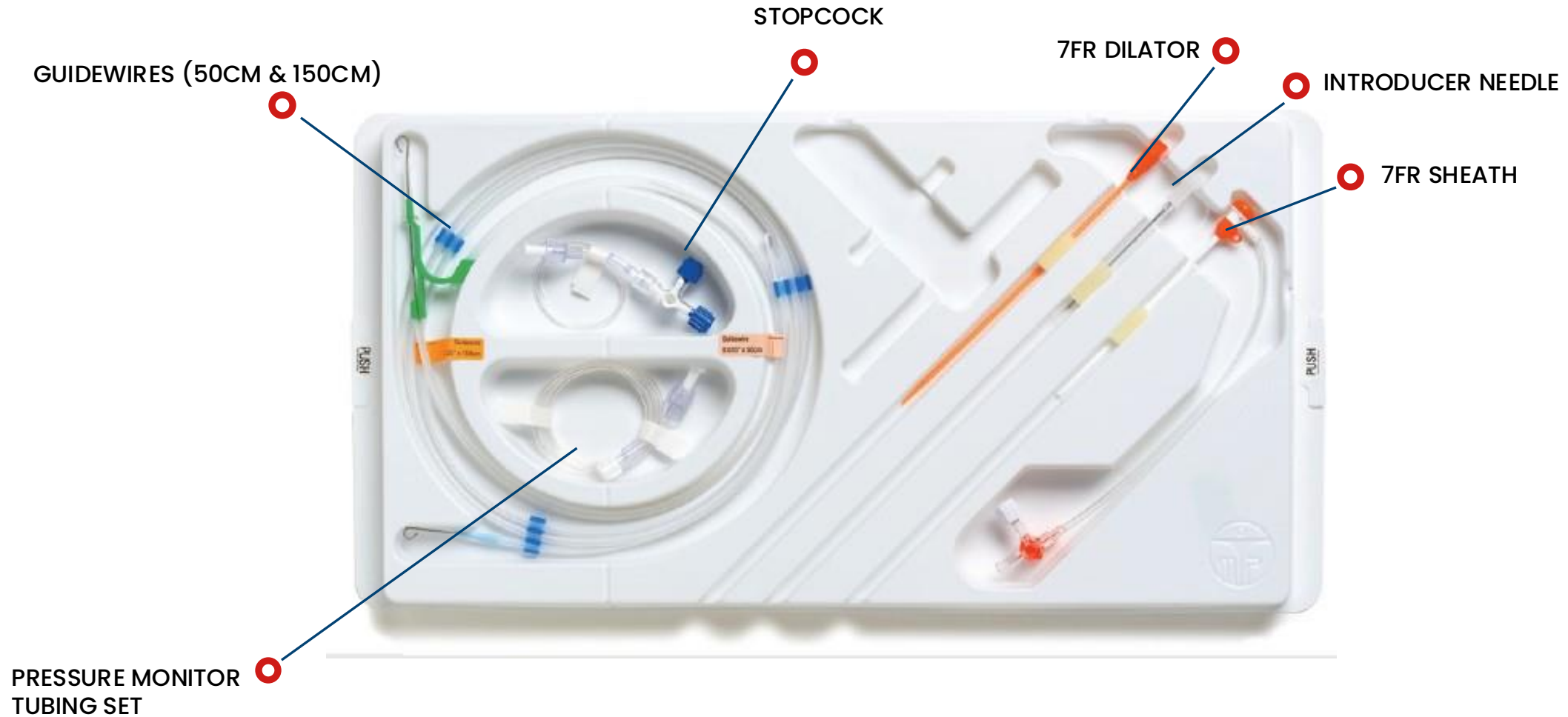
=

**8Fr Response
Performance in
a 7Fr device**



*Was compared to 8Fr Datascope balloon in clinical tests

ACCESSORY TRAY



GUIDEWIRES

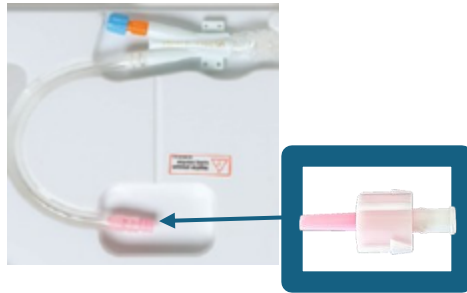
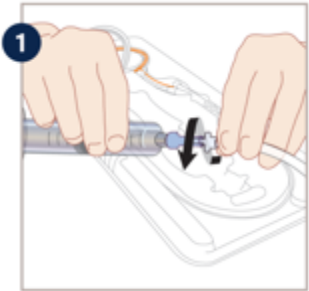


- 50 cm (0.035") Guidewire for single-operator insertion site preparation (optional)

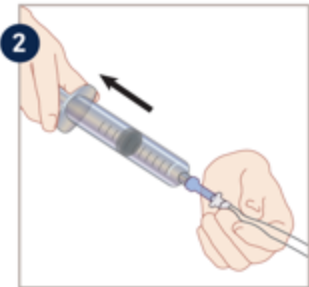
- 150 cm (0.025") Guidewire for dual-operator insertion site preparation and catheter insertion



CATHETER PREPARATION STEP 1



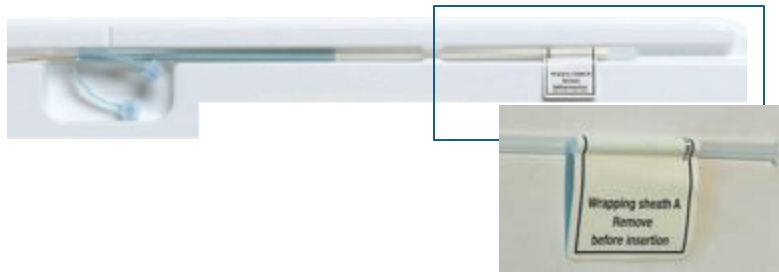
Connect the one-way valve to the catheter, matching pink to pink on the helium line



Apply **15cc** vacuum

Do not fully pull-out plunger! Do NOT exceed 15cc, which may prevent the balloon from inflating

CATHETER PREPARATION STEP 2 (UNIQUE TO INSIGHTRA)



After applying 15cc vacuum,
remove translucent wrapping
sheath

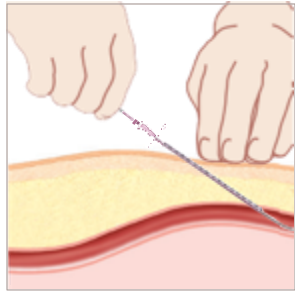


Slide Exosheath over balloon
leaving the soft tip exposed

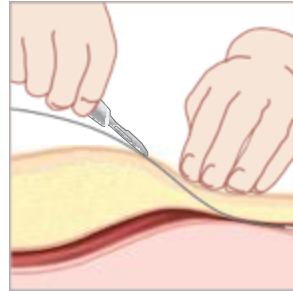
IAB Catheter is now ready for insertion

Catheter Insertion

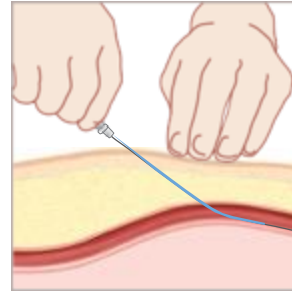
Sheathless Insertion



Insert needle at 45° angle or less, then insert guidewire.



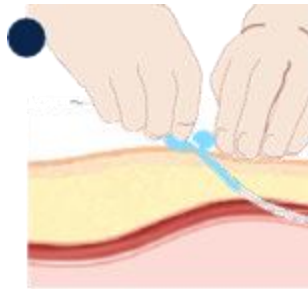
Make small incision at exit of guidewire.



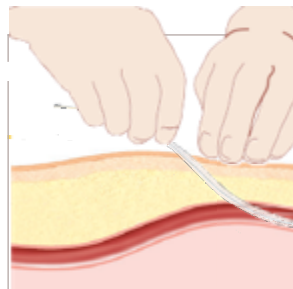
Insert vessel dilator over guidewire, tapered end first, then remove.



Spread tissue at incision to facilitate sheathless insertion.



As the balloon tip is inserted, pull back the Exosheath and advance the rest of the balloon into the artery in four strokes



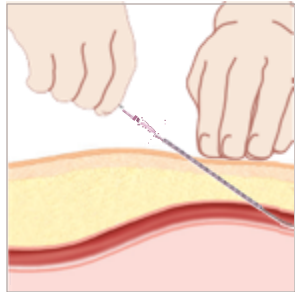
Advance IAB catheter into artery using short strokes until correct placement is achieved

NOTE: For Single operator the insertion site can be prepared with the 50cm (0.035”) Guidewire, which must be changed against the 150cm (0.025”) Guidewire, after the vessel dilator has been inserted

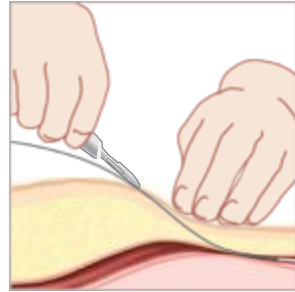
For dual operators, the 150cm Guidewire can be used for the whole procedure

Catheter Insertion

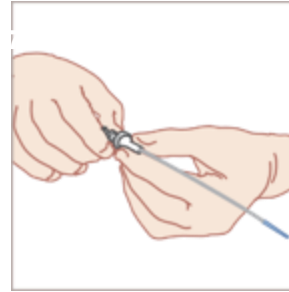
Sheathed Insertion



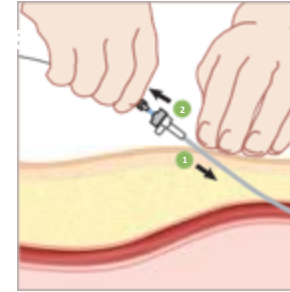
Insert needle at 45° angle or less, then insert 0.035 or 0.025" (0.06 cm) guidewire.



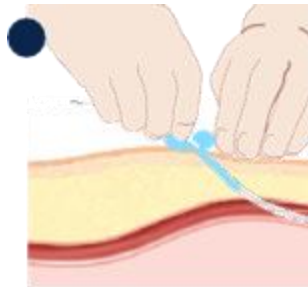
Make small incision at exit of guidewire.



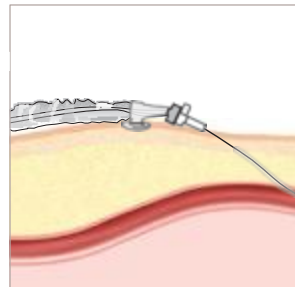
Insert introducer dilator into sheath hub and twist lock in place to secure.



- 1 Advance sheath over guidewire into artery using a rotary motion.
- 2 Withdraw introducer dilator leaving sheath in place.



As the balloon tip is inserted, pull back the Exosheath and advance the rest of the balloon into the artery in four strokes



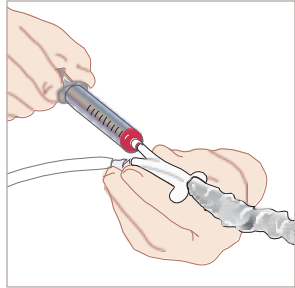
Advance IAB catheter through sheath using short strokes until correct placement is achieved, then advance sheath seal into hub of sheath.

NOTE: For Single operator the insertion site can be prepared with the 50cm (0.035") Guidewire, which must be changed against the 150cm (0.025") Guidewire, after the Sheath has been inserted

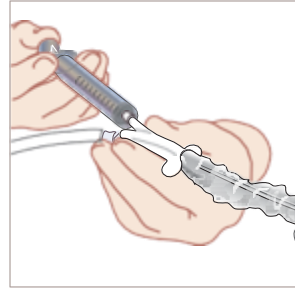
For dual operators, the 150cm Guidewire can be used for the whole procedure

Pump connection

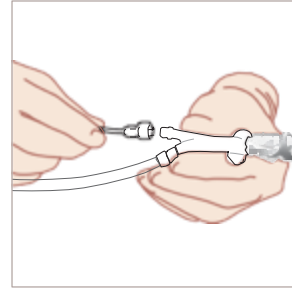
Setting up Pressure Monitoring



Remove guidewire and aspirate 3 cc of blood from inner lumen.

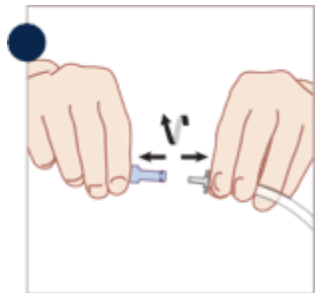


Manually flush inner lumen with 3-5 cc of flush solution.

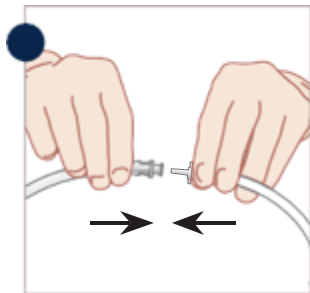


Attach a standard arterial pressure monitoring apparatus.

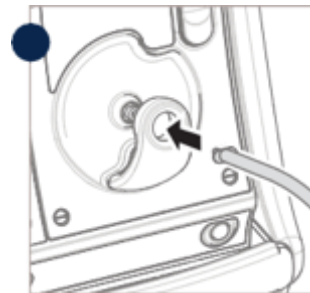
Connection to IABP Console



Remove pink one-way valve from IABP catheter.



Connect the appropriate helium line adapter for Datascope or Arrow



Connect helium line to Pneumatic Module of IABP Console



Arrow
Adaptor



Datascope
Adaptor