



Bedside insertion guide

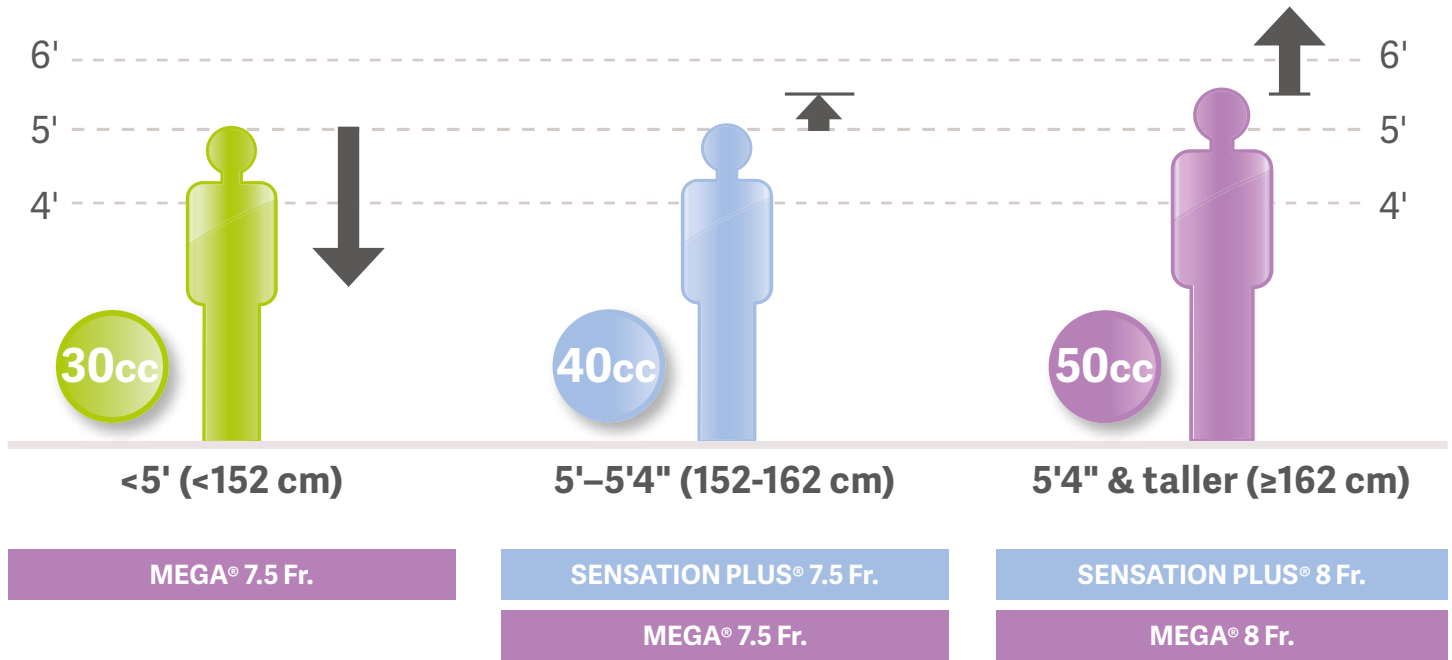
IAB catheter

List of items

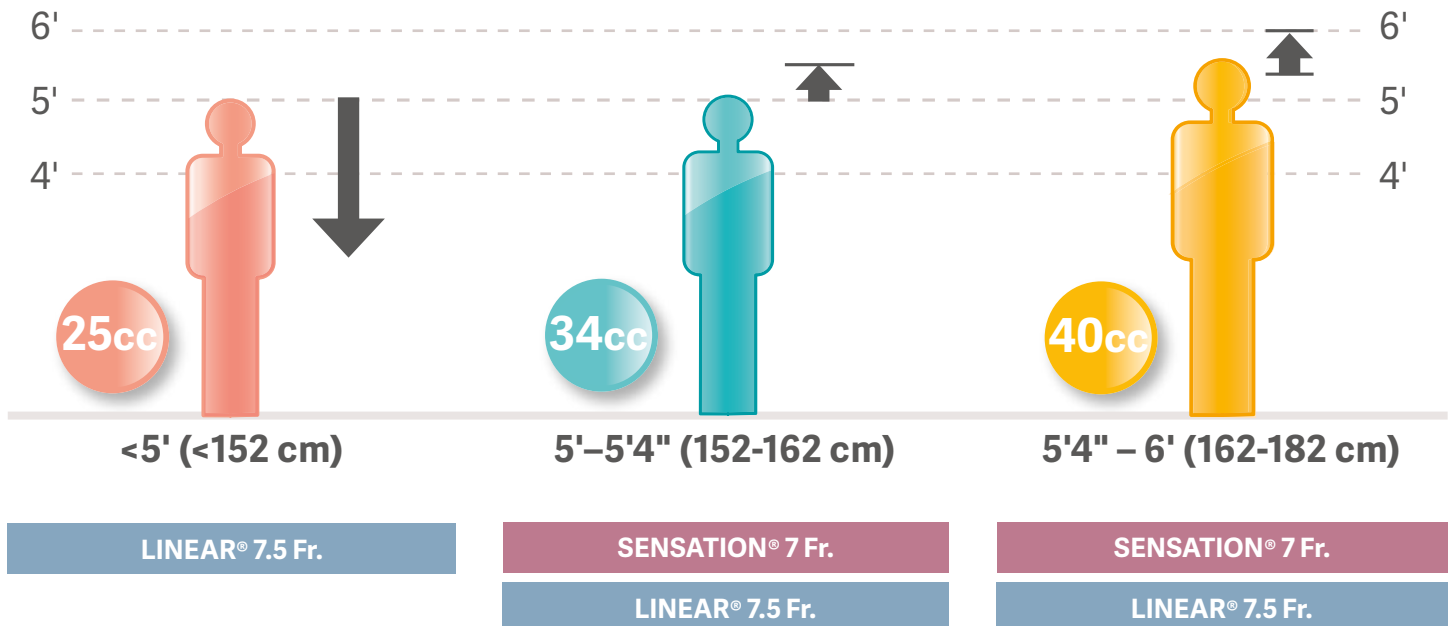
- Shave/prep kit with prep solution
- 1 basin of saline
- Local anesthetic (2% xylocaine) with syringe/needle
- EKG electrodes
- Dressing equipment
- Sterile drapes/towels, gloves, mask, caps
- Scalpel, blade
- 20cc syringe
- Lint-free sponges
- Kelly clamp
- Pressure bag with saline
- Getinge sterile insertion kit
- Getinge intra-aortic balloon catheter kit (select appropriate size)
- Intra-aortic balloon pump

IAB catheter sizing guide

Mega and Sensation Plus

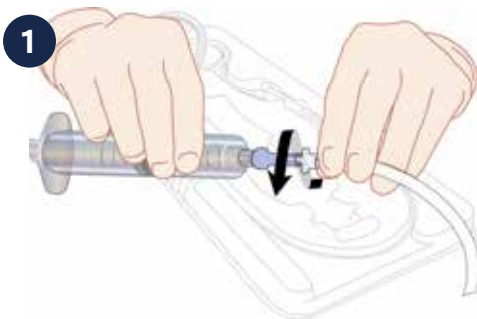


Linear and Sensation



Quick insertion guide

Preparing the catheter



1 Firmly attach the one way valve to the male luer of IAB catheter.

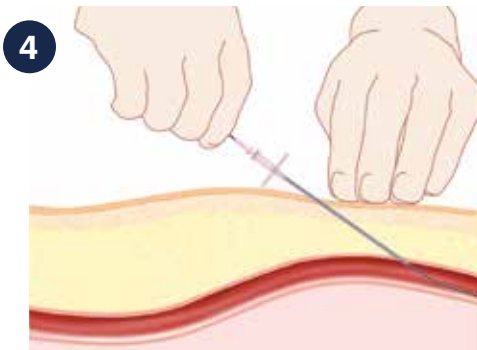


2 Apply a 30cc vacuum.



3 Remove syringe while keeping one way valve in place.

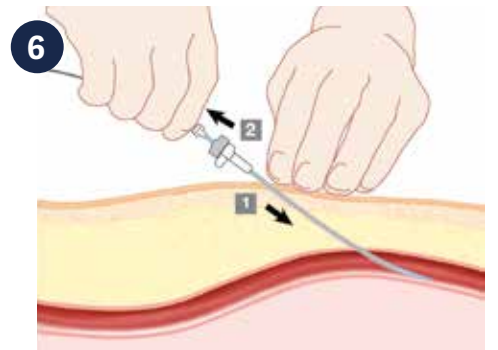
Inserting the catheter



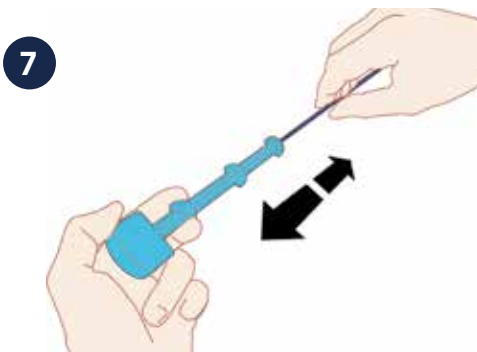
4 Insert needle at 45 degree angle or less, then insert 0.025" (0.06 cm) guidewire. Make a small incision at exit of guidewire.



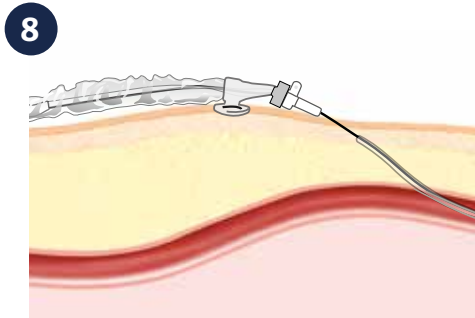
5 Insert introducer dilator into sheath hub and twist lock in place to secure.



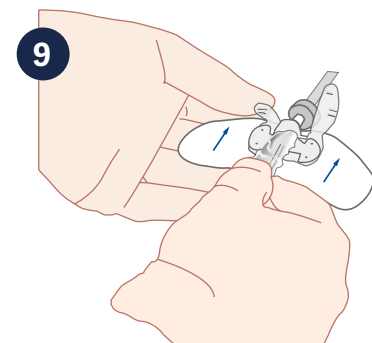
6 Advance sheath over guidewire into artery using a rotary motion. Withdraw introducer dilator leaving sheath in place.



7 Manually flush inner lumen with 3cc to 5cc of flush solution. Remove IAB catheter from the T handle by pulling straight out to avoid damaging it. **Do not dip, wipe, or handle balloon membrane prior to insertion.**

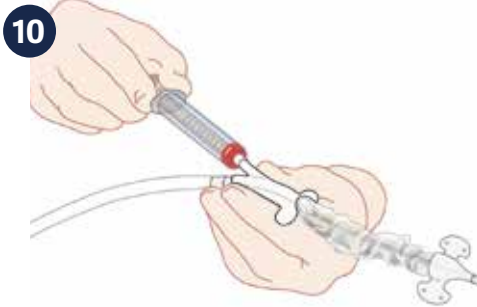


8 Advance the IAB catheter in short 1" strokes through the sheath into the artery until correct placement is achieved. Push the sheath seal into the hub of the sheath.



9 Secure IAB catheter to patient's leg using Statlock® IAB stabilization device or sutures (Sensation Plus includes Statlock® in IAB box).

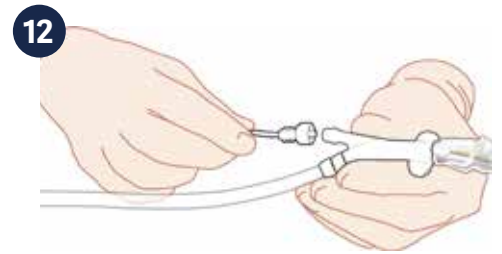
Pressure monitoring set-up



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



11 Manually flush inner lumen with 3 to 5cc of flush solution.

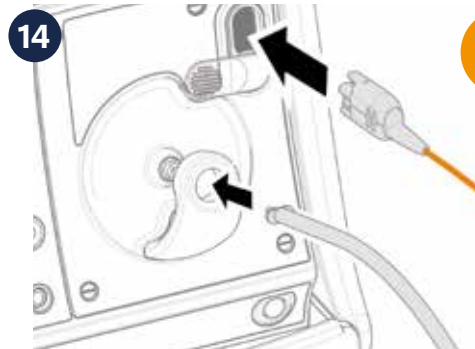


12 Attach a standard arterial pressure monitoring apparatus.

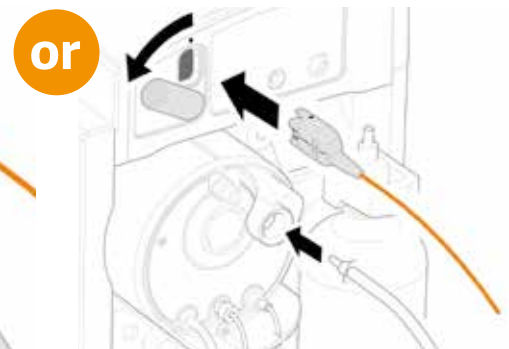
Connecting to IABP



13 Remove the one way valve from the IAB catheter. Connect the IAB catheter's male luer fitting to female luer fitting of catheter extender.



14 Connect male luer fitting of catheter extender to Pneumatic Module of Cardiosave. Connect arterial pressure cable to input port.



or
Connect male luer fitting of catheter extender to Safety Disk of CS300. Insert fiber-optic sensor connector into IABP's sensor input receptacle until it clicks.

Please see Instructions for Use for complete instructions.

Indications for Use

Acute Coronary Syndrome

- Refractory unstable angina.
- Impending infarction.
- Post-infarction angina or threatening extension of myocardial infarction (MI).
- Complications of acute MI.
- Support for diagnostic percutaneous revascularization and interventional procedures.
- Ischemic related intractable ventricular arrhythmias.

Complications of heart failure

- Cardiogenic shock.
- Refractory left ventricular failure.
- Cardiac contusion with left ventricular dysfunction.

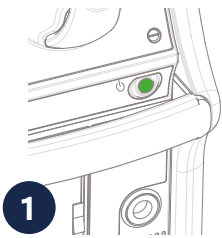
Cardiac and non-cardiac surgery

- Weaning from cardiopulmonary bypass (CPB).
- Cardiac support for non-cardiac surgery.
- Prophylactic support in preparation for cardiac surgery.
- Post-surgical myocardial dysfunction/low cardiac output syndrome.
- Mechanical bridge to other assist devices.
- Cardiac support following correction of anatomical defects.

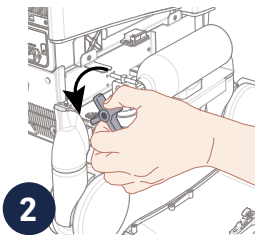
FDA's Final order Dec 2013: <https://www.federalregister.gov/documents/2013/12/30/2013-31218/cardiovascular-devices-reclassification-of-intra-aortic-balloon-and-control-systems-for-acute>
FDA Executive Summary Classification of IABP December, 2012

*FDA approved indications

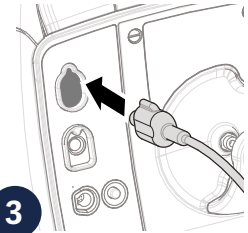
Initial set-up — Cardiosave IABP



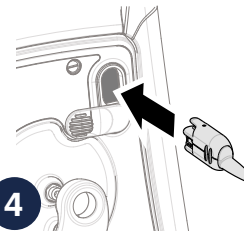
1
Press power button to turn IABP on.



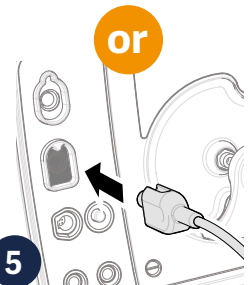
2
Open helium tank (if not already opened).



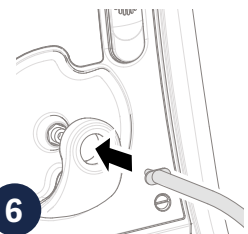
3
Connect ECG cable.



4
Connect fiber-optic sensor connector for Getinge fiber-optic IAB.



5
Connect pressure cable for conventional IAB.



6
Connect IAB.



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⚠ CAUTION: Federal (US) law restricts this device to sale by or on the order of a physician. Refer to Instructions for Use for current indications, warnings, contraindications, and precautions.