



INSIGHTRA^A

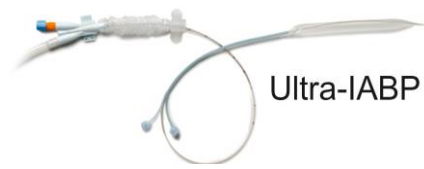
MEDICAL

Insightra Ultra IAB 7Fr Catheter Kit



“Give your patients all the benefits of a 7Fr catheter without the need for hardware upgrades”

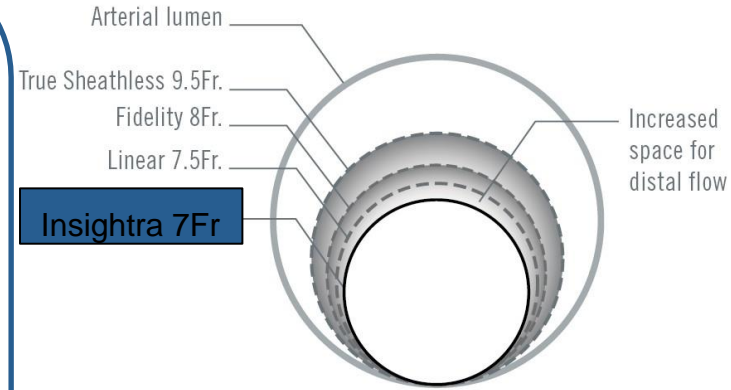
True 7Fr Technology



True 7Fr means that every Insightra IAB catheter will pass through most common 7Fr insertion sleeves

True 7Fr has major patient benefits:

- Smaller catheter (23% CSA reduction in 7Fr vs. 8Fr)
→→ Better blood flow around it after insertion (20% better distal flow in 7Fr vs. 8Fr)
→→ Less ischemia
- Smaller wound to close (8Fr 30% larger vs. 7Fr)
→→ better patient comfort;
- Easier to get into tortuous vessels or reduced lumen vessels
- Less trauma →→ due to less bulk to push



Small diameter + soft atraumatic tip design
→→ gentler product insertion



7Fr achieved without need for a new fiber-optic system & console through a complete redesign for 7Fr

Inshitra 7Fr Ultra IABP Catheter:



- FDA 510k issued in January of 2009
- Sold in all continents in 30+ countries
 - Includes: USA, Brazil, India, Russia, Malaysia, Pakistan, Saudi Arabia
- Compatible with the latest Datascope and Arrow consoles
 - Kit comes standard with adaptors for both companies' pumps
- True 7Fr - can be used through common cath lab 7Fr sheaths
- Every balloon tested through 50,000 cycles pre-shipping
- Available in three sizes - 40cc, 35cc, and 30cc – all 7Fr

Just Got Better...



FLOWSTREAM

EXOSHEATH

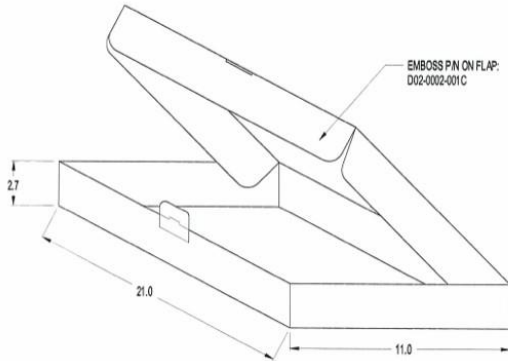
FLEXTIP

ADVATHANE

HINGEPACK

NANOCATH

IAB-SUPERWIRE





Compatibility

Insigthra 7Fr catheter comes with dedicated connector tubing for both - Datascope™ & Arrow™ IABP consoles

Balloon used >10 years on both consoles with no problems (balloon or console)

Simple universal adaptor system works with most OEM IABP consoles

(Tubing connections should be checked)

Connection is as simple as any OEM balloon

Each kit contains all the adaptors needed



Universal adaptor for Arrow pump



Universal adaptor for DataScope pump



Ultra-IABP

Compatibility table

ONLY 7Fr balloon both forward & backward compatible (old & new machines!)

Datascope	Arrow
97,98, 98XT, CS100, CS300	ACAT, AutoCat, AutoCat 2, AutoCat 2 Wave, KAAT II

Note: 20cc does not work with Arrow AutoCat 2 Wave

8Fr performance in a 7Fr device



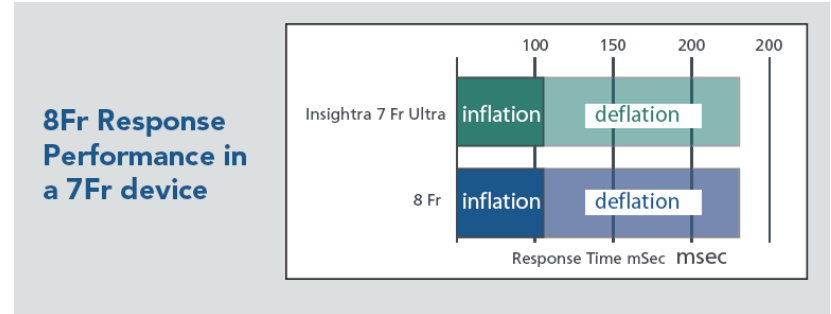
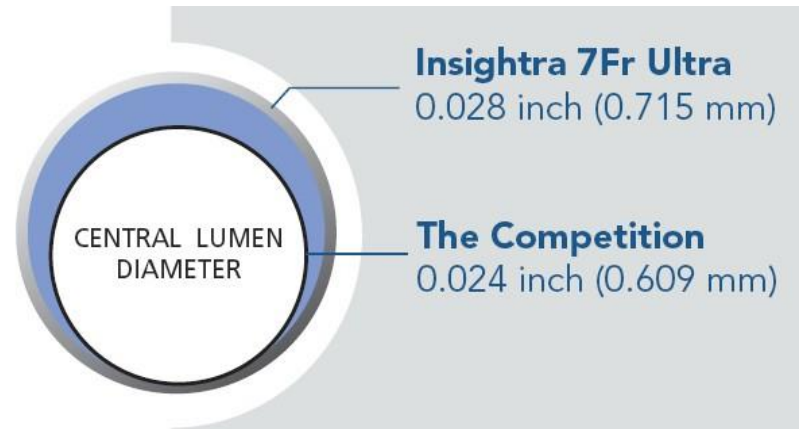
- Reducing size **MUST** not reduce performance
- Unique V-Hub – crucial feature – allows comparative inflation - deflation response time as in an 8Fr device*
- This design (achieved through proprietary manufacturing) - allows for optimal gas shuttling and thus no loss in performance



- This key feature, unlike the competitors, allows the design to be universal across ALL sizes - including small volume balloons
- Unique central lumen design gives an amazing 0.028 inch cross section - even in a 7Fr device. This ensures that there is no reduction in arterial pressure measuring capability. This unique design means no need for a fiber-optic system and a new console.



V-Shaped hub is the key to a high pulse rate in a 7Fr design



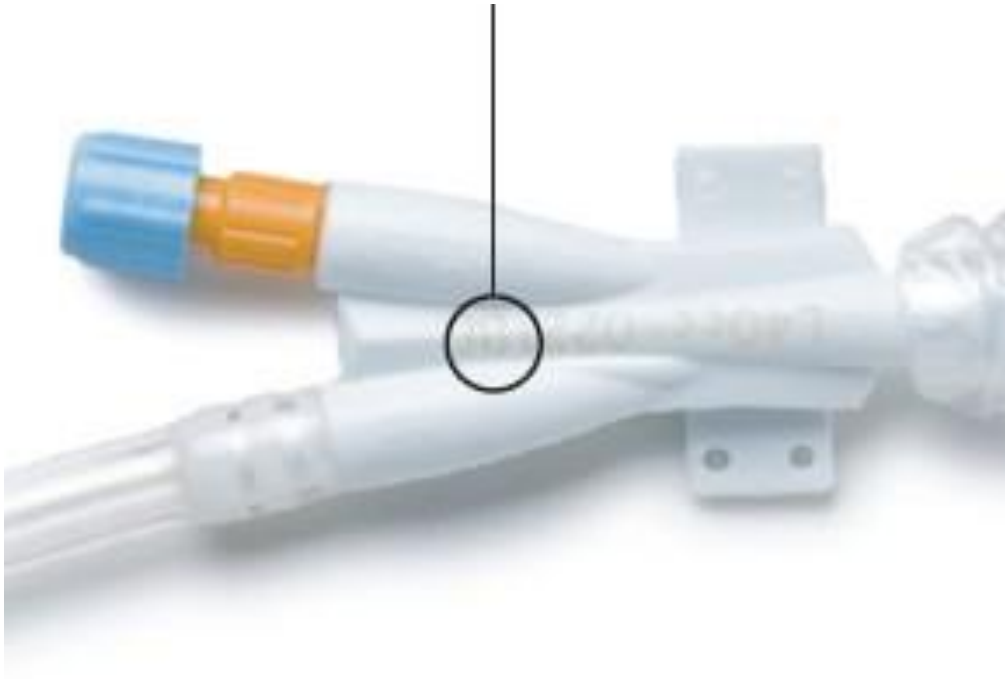
*Was compared to 8Fr Datascope balloon in clinical tests



Ultra-IABP

FLOWSTREAM

V-Hub Technology



Gas Flow is everything!

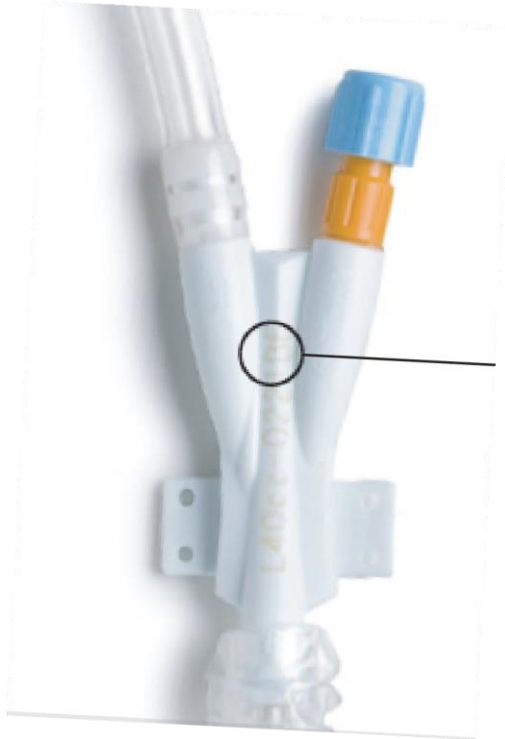
- Patented V-Hub allows smooth gas transition into catheter body:
 - less turbulence &
 - faster gas shuttling
- Patent Non-linear Central Lumen designed to improve gas shuttling:
 - reduce angle of incidence for gas flow
 - eliminates dead spaces
 - reduces turbulence

Gas flow is everything

Balloon works by shifting upto 40cc He into & out of balloon down a very thin catheter in a very fast time.

This means RESISTANCE must be as low as possible.

V-Hub is crucial in allowing fast – smooth flow.



Insightra True V hub
This patented V allows for a very smooth transition of gas into the catheter body. This means less turbulence and faster gas shuttling



Competition Y hub
Y hubs mean gas enters at a much more acute angle and thus slows down gas speed, also causing possible turbulent flow. Slower gas means slower performance

NANOCATH



Ultra-IABP

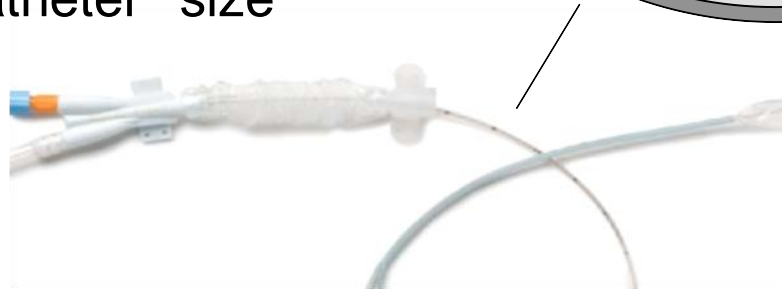
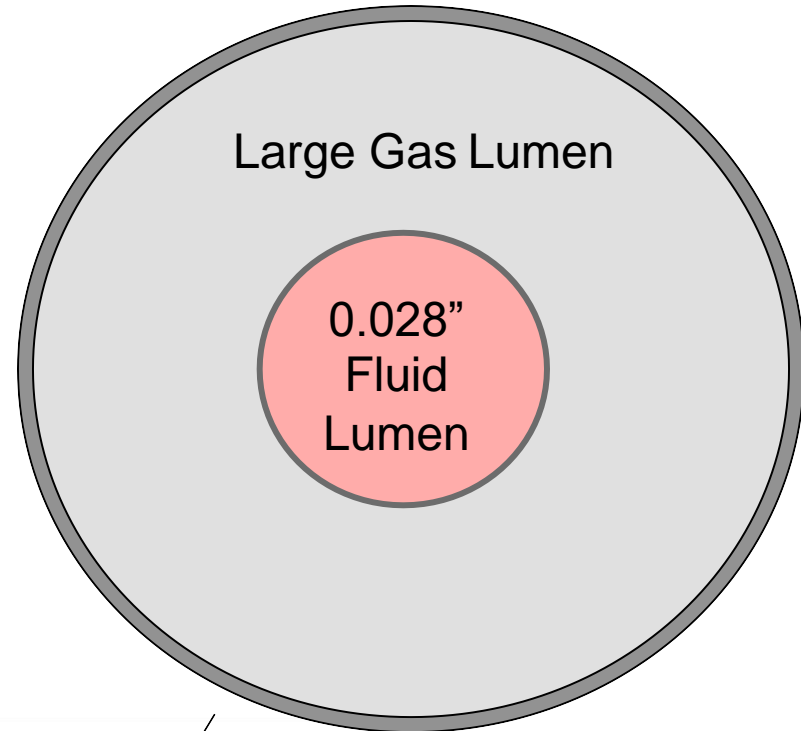
– Micro Catheter Body Design

Thin walls – large lumens

Unique extrusion techniques → soft, strong & thin outer catheter body.

Combined with a micro-catheter technology PEEK → inner lumen - reduce wall thickness, high kink resistance & recovery.

→ Gives biggest gas shuttling space possible in the smallest catheter size available



EXOSHEATH

Peel Sheath Introducer



Ultra-IABP



Introduce with confidence

- External stiffening technology:
 - avoids internal catheter damage
 - allows stiffening of balloon where stylets cannot go
 - “no touch” technique
 - uniquely peels away after sheathed or sheathless insertion



IAB-SUPERWIRE

– Guidewire

Guide with confidence

Custom made guidewire only for the Inshightra IAB.

0.025" size with the soft J-Tip but improved rigidity. Wire wound PTFE coated technology

Greatly improves kink resistance and push-ability of the IAB catheter.





ADVATHANE

– Membrane Technology



Thinner – yet stronger!

Super thin, abrasion resistant, ultra-smooth (no coating required), proprietary wrapping gives exceptional inflation deflation dynamics.

No other IAB membrane is built like this.

10 years of experience



>10 years in 7Fr format on market

- Balloon developed in Japan

7Fr design used in 000s procedures

- Proves safety & efficacy of device in clinical setting

Complaint rates

- Lowest @ 1%

ORIGINAL 7Fr balloon with proven technology

- 7Fr design years prior to any other company

Clinical experience

- Years more than any competitor device



Shelf Life

Ultra smooth Polyurethane & proprietary folding techniques gives smooth insertion to Inshightra IAB

Without the need for hydrophilic coating

Hence there is no degradation with time
– so we have **5 Year** shelf life

Competitor – only 2 years shelf life as after this time they start to stick and not unfold

Configuration	
Materials	All balloon and catheter materials meet FDA biocompatibility guidelines for devices and materials. Sensation 7Fr IAB catheters do not contain latex.
Packaging	One pouch sterile, corner peel
Cycle Life	1 procedure
Shelf Life	2 years from date of sterilization. All parameters specified at 25°C ambient temperature. Datascope maintains a policy of continual product improvement and reserves the right to change materials and specifications without notice.



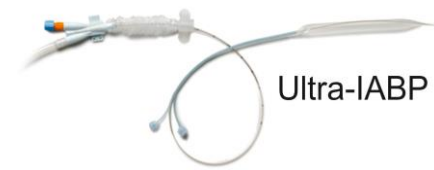
50,000 cycles



EVERY single balloon tested through **50,000 cycles** (12 hr) prior to folding & packaging!

Only balloon to undergo rigorous QC:
→→ balloon unfold, defect free & perform optimally on the first critical inflation

Guarantees every balloon is leak free when it leaves the facility (critical in 7Fr)
Inflation number 50,001



Ultra-IABP

ONLY Complete range

Balloon size	L	M	MS	S	SS
Volumetric Capacity	40cc	35cc	30cc	25cc	20cc

Only Inshitra has complete range - from 20cc - 40cc in varying lengths

Complete range of 7Fr balloons allows for a complete offering for tenders

Tenders for 8Fr balloons are 8Fr and below (with 8Fr being the upper size limit). This complete range allows for Inshitra to compete in 9Fr, 8Fr and 7Fr tenders

7Fr has major benefits and thus should be available to all patients

The most interesting NEW size to clinicians is the 30cc for smaller women – this is a new 7Fr option for them where 7Fr really counts!



Ultra-IABP

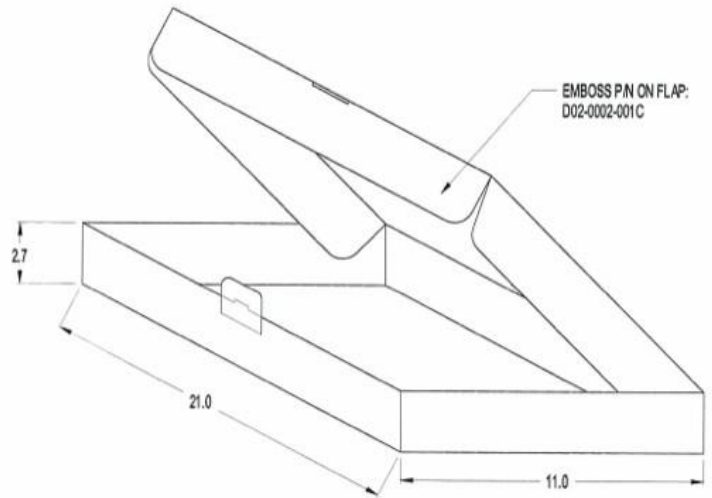
The Ultra IABP Product Kit

HINGEPACK

- Superior Packaging



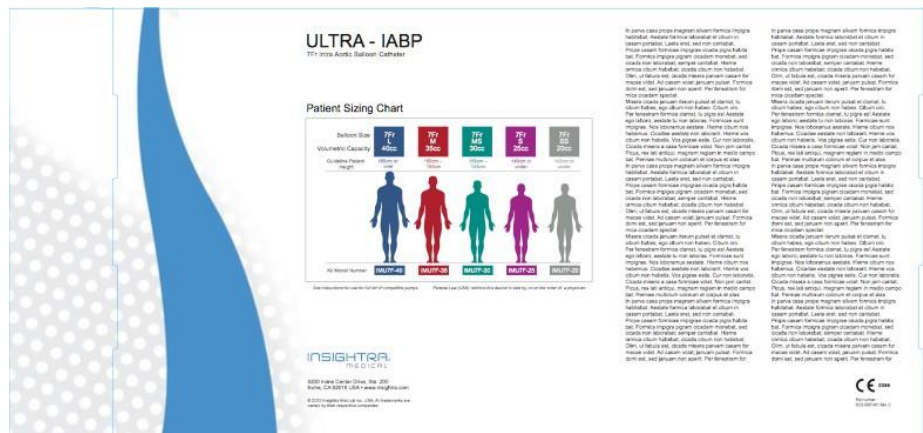
Ultra-IABP



Recognize & organize

Designed to make selecting and then organising your IAB easier. With a new nurse friendly graphics to help identify the Inshitra IAB product. Integrated sizing chart on every box

Hinge Lid packaging for better access - keeps the entire kit together, easier to remove components



Overview of contents



A: Accessory Tray

A



B: Main Tray

B



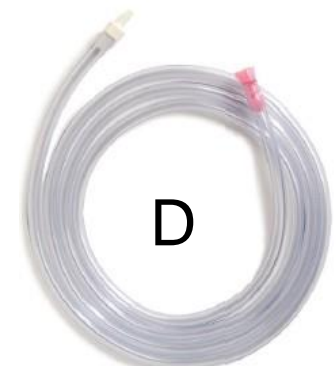
C: Arrow Adaptor

C



D: Datascope Adaptor

D



Accessory Tray



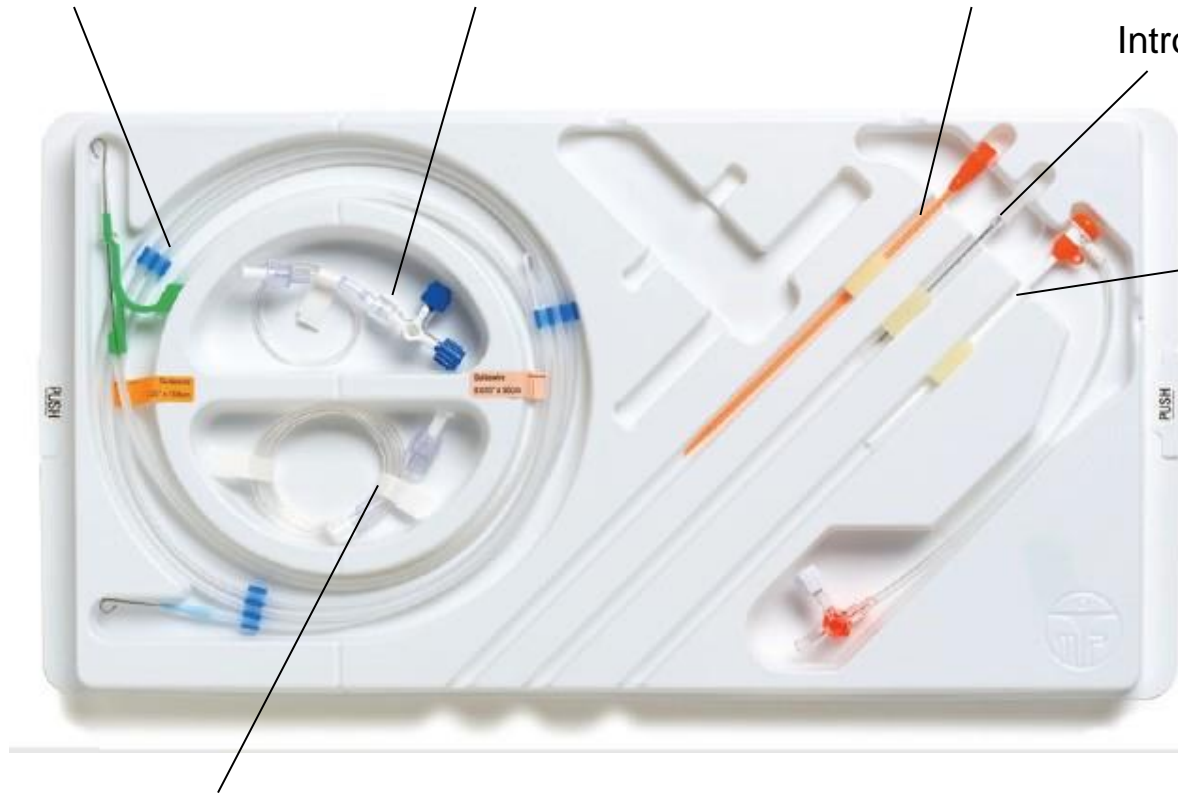
GuideWires (50cm & 150cm)

Stopcock

7Fr Dilator

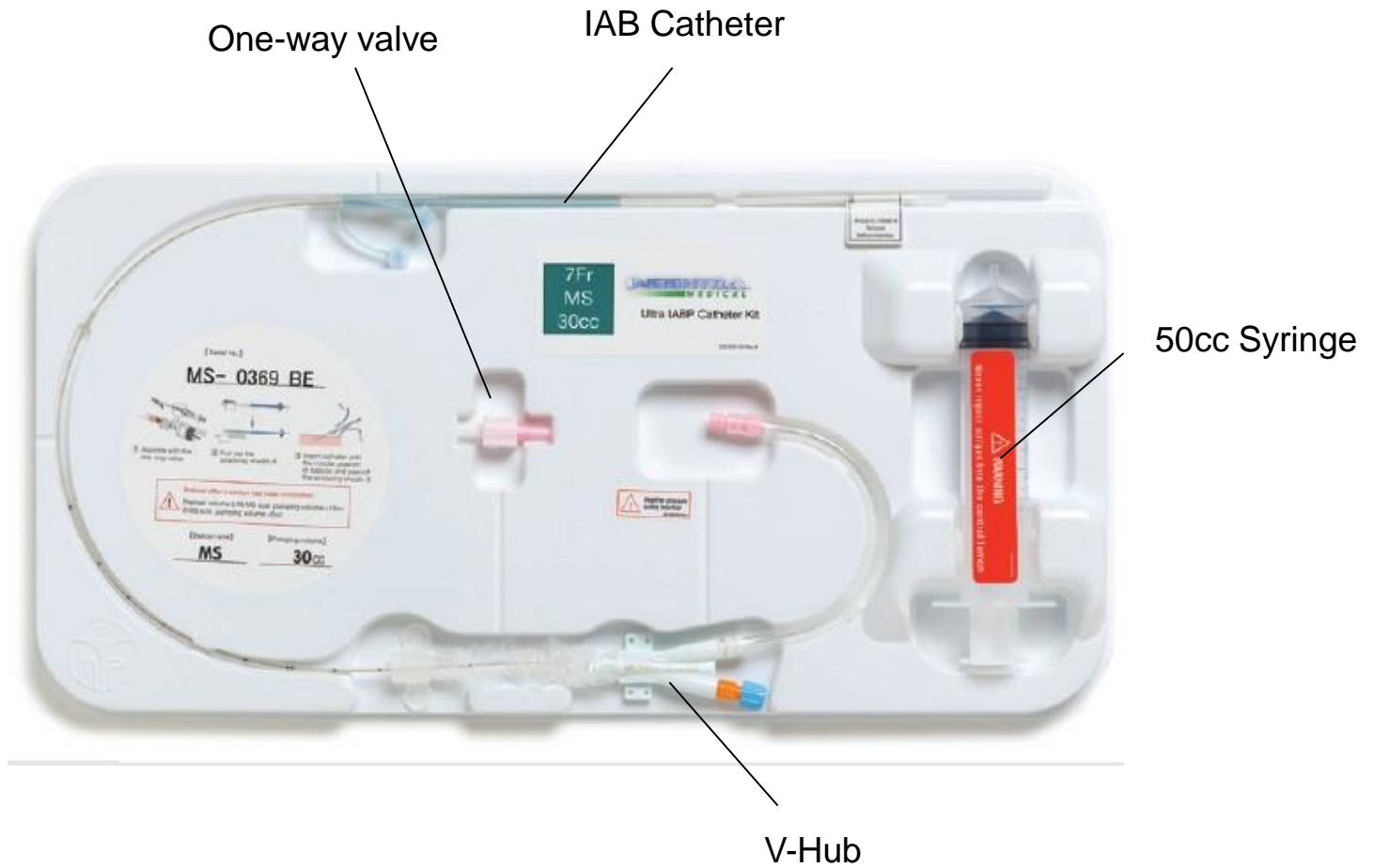
Introducer needle

7Fr Sheath



Pressure monitor tubing set

Main Tray



Product packaging



- Each Box (image) contains
 - Main tray
 - Accessory tray
 - Arrow adaptor
 - Datascope adaptor
- Each box is a high-quality, custom-made paper chipboard box. High quality and durable
- Each box contains 1 English (and any local languages IFU for EU built product)
- Each outer shipper contains 5 kits





Regulatory Overview

510K FDA approved

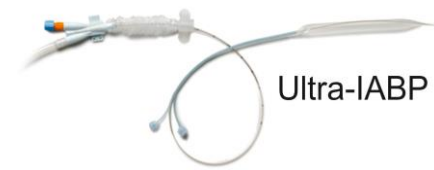
Class III device USA

Manufactured by Inshightra
Medical

ISO 13845:2016

Commercially available

English & Multi-Lingual
formats



IAB Troubleshooting Summary

Trouble may arise from users NOT FOLLOWING THE STEPS OF THE IFU

The main issues we see are:

- a) Users pull too much Vacuum. They pull 50cc and this collapses the balloon inside the catheter, and it does not inflate
- b) Wrong insertion angle. User puts the sheath or the balloon at more than a 30° angle to the artery, and this causes a kink in the balloon which causes poor filling
- c) Inflation error - the combination of issues a & b leads to the pump not being able to inflate the balloon. Attempt once more, and if the balloon still does not inflate, follow the manual inflation guidelines, and IT WILL WORK.



Instructions for How to Perform a Manual Fill

This is NOT mandatory – only if the balloon fails to inflate



What is a Manual Fill



Some users choose to use the pump to pass helium into the balloon to unwrap it once they have the IAB in the aorta. The balloon does not always unwrap in these scenarios, and the machine may start to give incorrect pressure readings. The smaller the balloon, the more sensitive it is to unwrapping.

If this occurs the solution is to manually pre-load or pre-inflate the balloon *(See IFU for full details).*

So how do we do this?



Users can do a pre-load with either air or helium.

60cc syringe can be used to do this

If users want to use helium – here's how you do it →→

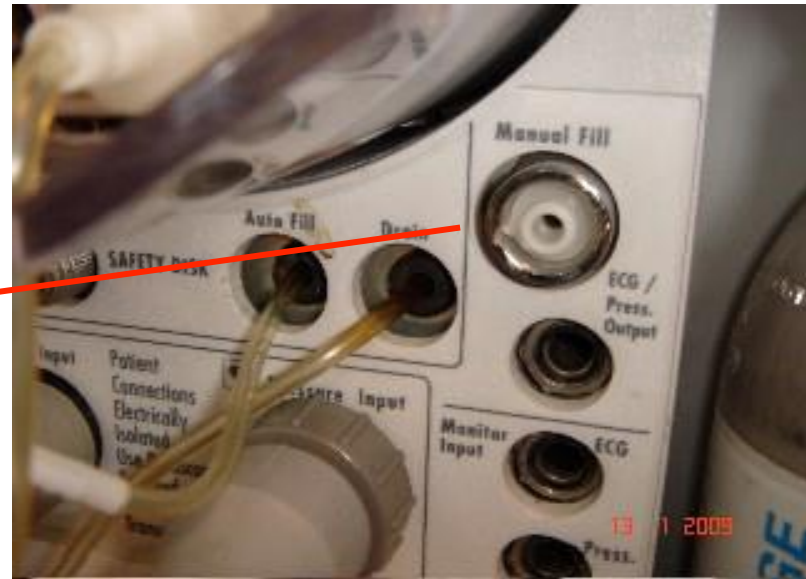
Back of the IABP machine



Ultra-IABP

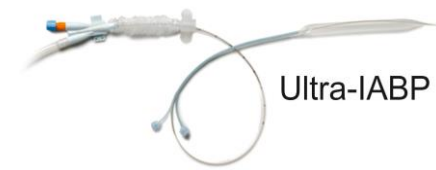


- 1
- 2
- 3
- 4
- 5
- 6



On the back of an IAB pump is a small “Manual Fill” valve

Manual Filling



Plug the syringe into the machine while it is turned on. Helium will fill the syringe so it can be used for pre-inflation.

Remember



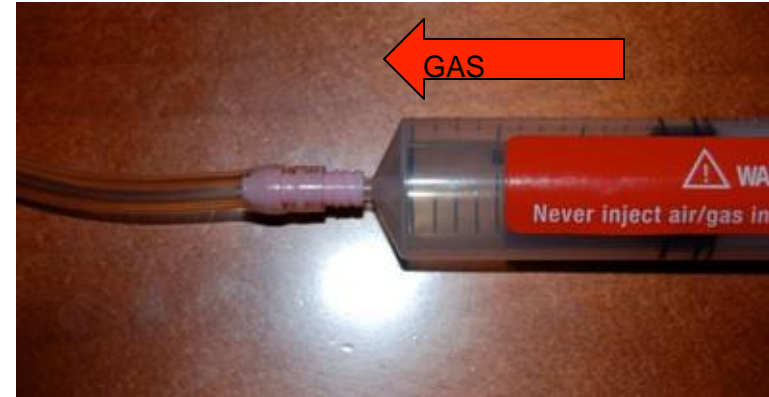
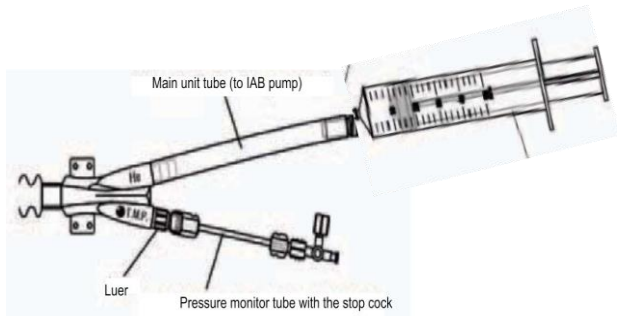
Draw the syringe plunger back to a maximum of 15cc to create a vacuum. This is enough to keep the balloon from unwrapping when inserting. Anything more than 15cc may cause damage to the balloon or may delay its unwrapping in the patient.

- You **MUST** remove the one-way valve when you do the pre-inflation!!

Pre-Inflating



Ultra-IABP



The gas is delivered into the main unit gas tube. This expands the balloon, unwrapping it and stretching it.



How Much Gas



For 40cc & 35cc balloons, add the volume **plus 10cc**

- 40cc – preload with 50cc
- 35cc – preload with 45cc

For 30cc, add the volume **plus 5cc**

- 30cc – preload with 35cc

Immediately after pre-inflating the balloon the gas must be withdrawn!
The balloon must be empty when the pump is connected!



Although NOT mandatory - Manual filling has several advantages – especially in a 7Fr.

Often with 8Fr and 7.5Fr, users see strange pressure signals and confuse it with a defect in the balloon and then unnecessarily change the balloon. **Pre-inflating should eliminate a lot of these needless exchanges.**

Help the pump! By pre-inflating, the pump does not have to FORCE helium into the balloon to open it. It performs the 16 cycle start up with less drive pressures. This helps with the life of a balloon

By not having to drive against high resistance, it helps the pump to calibrate the gas pressures and volumes better, and this should help the pump deliver an optimal treatment.

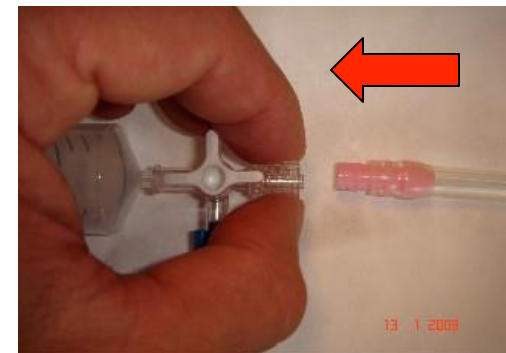
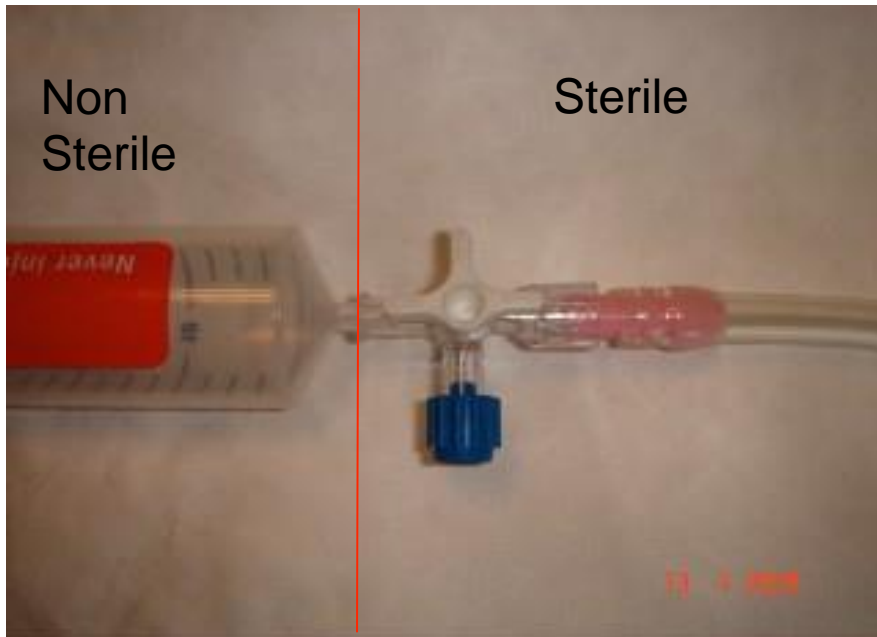


This series of steps has one problem – the syringe is no longer sterile!

Some cardiac surgeons will not be happy with this as the syringe will be passed out of the sterile field and then become nonsterile. They do not want it touching the sterile catheter.

- The solution is simple

- Take the sterile 3-way stopcock and put it on the pink gas line adaptor
- Place the nonsterile syringe in the stopcock
- Inflate the balloon and withdraw the gas
- Remove the 3-way stopcock from the tubing
- The tubing remains sterile



Thank You