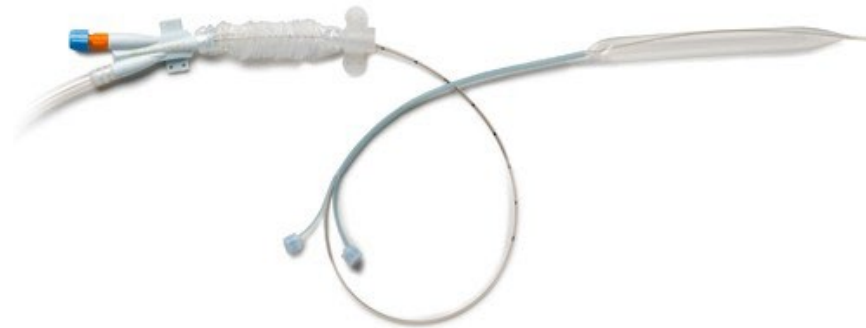




INSIGHTRA^A

MEDICAL

Insightra Ultra IAB 7Fr Catheter Kit

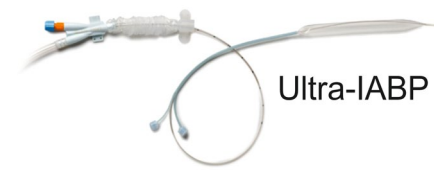


“Give your patients all the benefits of a 7Fr catheter without the need for hardware upgrades”

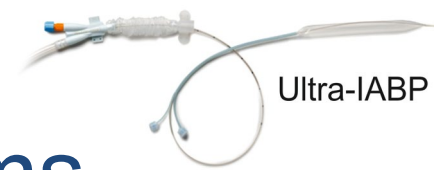
Inshitra 7Fr Ultra IABP Catheter:



- 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 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

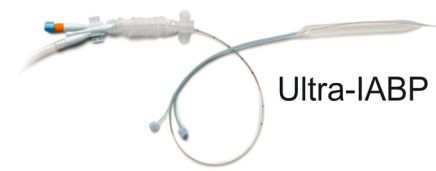


- Brief Introduction to IAB Therapy
- Benefits of 7Fr Technology
- The Inshightra Ultra 7Fr IAB Catheter Product Overview
- The Ultra IABP Kit
- Instructions for How to Perform a Manual Fill
- Clinical & Market Evaluation Summaries



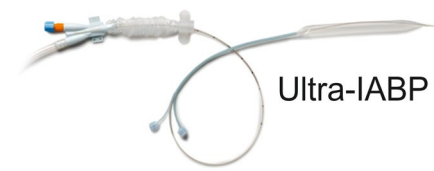
Abbreviations and Acronyms

MI	Myocardial Infarction
AMI	Acute Myocardial Infarction
CS	Cardiogenic Shock
CPB	Cardiopulmonary Bypass
CABG	Coronary Artery Bypass Graft
CSA	Cross Sectional Area
IAB	Intra-Aortic Balloon
IABP	Intra-Aortic Balloon Pump
IFU	Instructions for Use
PVD	Peripheral Vascular Disease
LVAD	Left Ventricular Assist Device
STEMI	Segment Elevation Myocardial Infarction



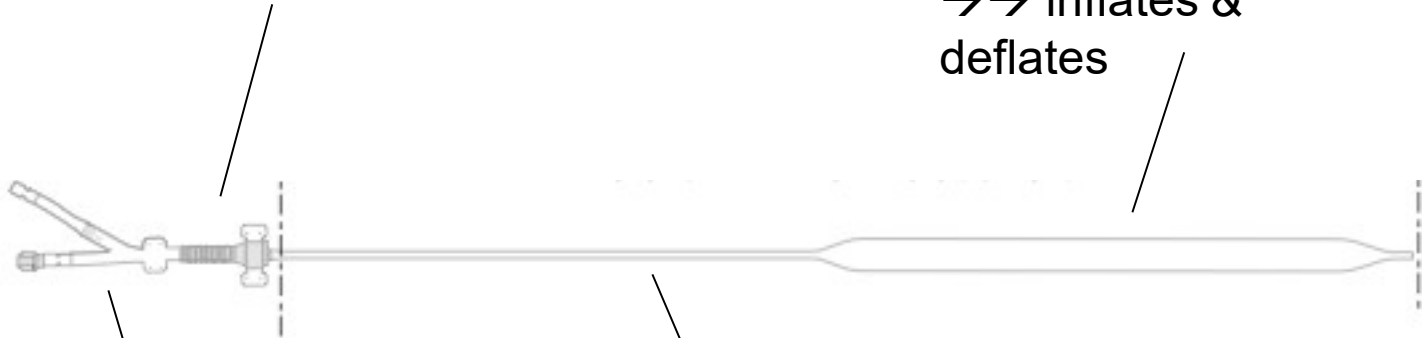
Brief Introduction to IAB Therapy

IABP Catheter



Plastic sheath →→ sterility
with suturing tabs

Polyurathane balloon
→→ inflates &
deflates



Catheter body (9Fr, 8Fr, 7.5Fr, 7Fr in diameter)

V or Y Hub:

One arm →→ gas in-out

Other arm →→ guidewire

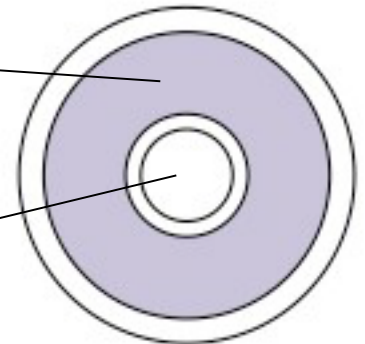
&

central arterial pressure

measurements

Gas lumen.
CSA determine how
fast gas can flow

Central lumen for
guidewire and then
measuring arterial
pressure



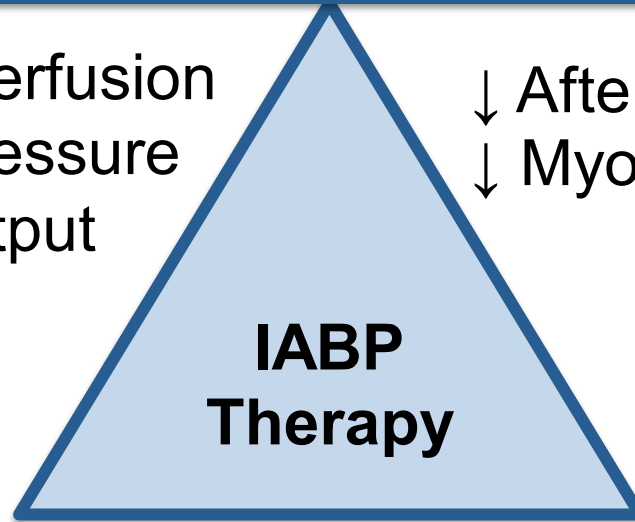
Cross section of catheter body

Mechanical support to failing heart



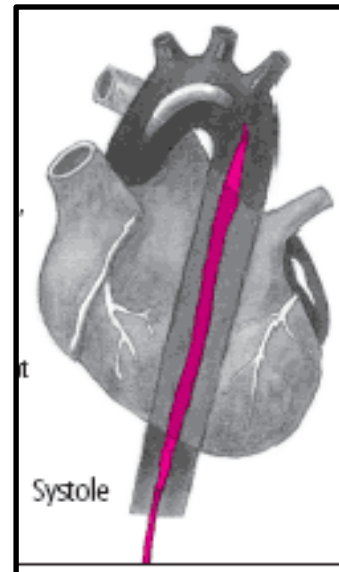
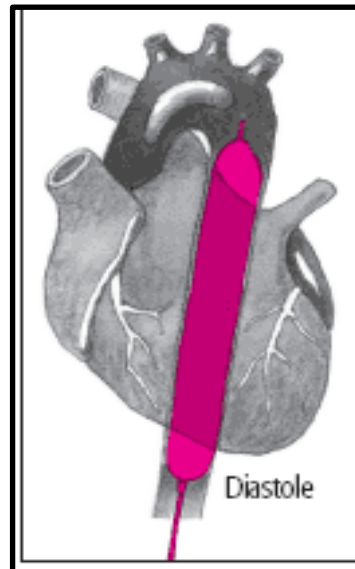
↑ Coronary Perfusion
↑ Diastolic Pressure
↑ Cardiac Output

↓ Afterload
↓ Myocardial O₂ Demand



Counterpulsation:

Balloon inflates when heart in diastole & deflates when heart in systole

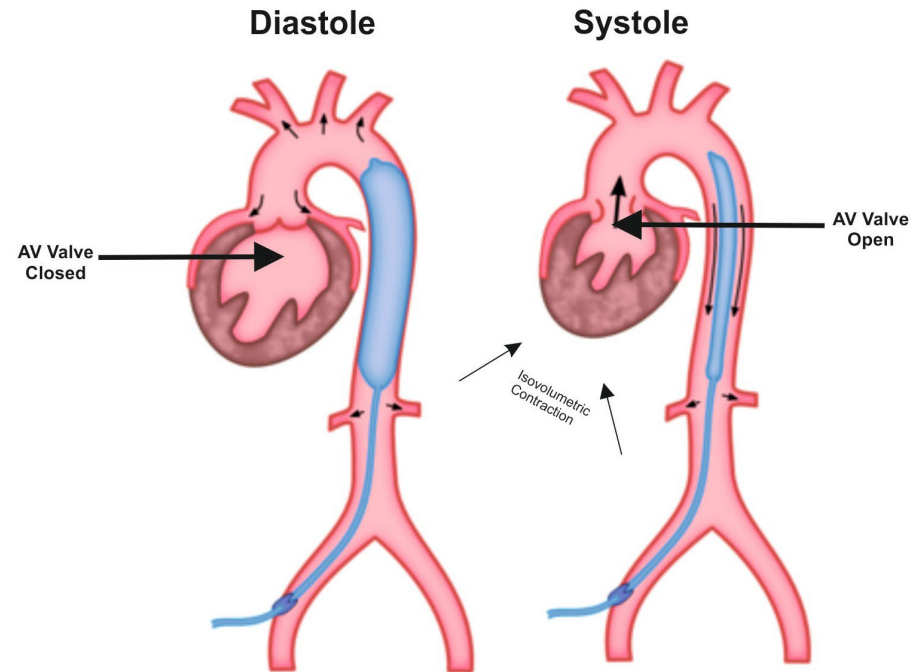


Diastole:

AV closure & balloon inflates
pushing blood into coronaries
→→ increasing myocardial
perfusion
→→ Increasing blood supply to
coronaries first helps heart
working to its full.

Systole:

Isovolumetric contraction of LV;
where 90% of O₂ consumption is
needed to open AV. We need to
shorten this phase through
counterpulsation by deflation of
balloon & reducing afterload thus
heart needs to work less to
overcome the afterload.



Balloon Inflation- Increased blood flow to coronaries & ischemic part gets perfused.

Balloon Deflation- Reduces resistance, allows heart to work more efficiently with less myocardial O₂ demand.

Physiological Effects - IAB

Inflation - Onset of Diastole

↑ Coronary Blood Flow

↑ Diastolic Pressure

Potential of ↑ Coronary
Collateral Circulation

↑ Systemic Circulation

Deflation - Onset of Systole

↓ Afterload

Isovolumetric Contraction
Phase ↓

↑ Stroke Volume

↑ Cardiac Output

Indications – Inshightra IABP Catheter Kit

Refractory Unstable Angina

Impending Infarction

Acute Myocardial Infarction Refractory

Ventricular Failure

Complications of Acute MI (ie. Acute MR or VSD or papillary muscle rupture)

Cardiogenic Shock

Support for diagnostic, percutaneous revascularization & interventional procedures

Ischemic related intractable ventricular arrhythmias

Septic Shock

Intraoperative pulsatile flow generation

Weaning from CPB

Cardiac support for non-cardiac surgery

Prophylactic support in preparation for cardiac surgery

Post-surgical myocardial dysfunction/ low cardiac output syndrome

Myocardial Contusion

Mechanical Contusion

Cardiac support following correction of anatomical defects

ACCF/AHA Guidelines Affirm IABP as “First Line” Device in Cardiogenic Shock



American College of Cardiology Foundation (ACCF)/ American Heart Association (AHA) Task Force **ranked IABP ahead of LVAD for treatment of cardiogenic shock:**

“Use of IABP counterpulsation can be useful for patients with cardiogenic shock after STEMI who do not quickly stabilize with pharmacological therapy” Class IIa, evidence level B

“Alternative LVAD for circulatory support considered in patients with refractory cardiogenic shock” Class IIb, evidence C

2013 ACCF/AHA Guideline for the management of ST-elevation myocardial infarction. P.T. O’Gara, et al. Circulation. December 17, 2012

ESC Rates IABP Shock Clinical Data “Highest” of All Cardiac Assist Devices



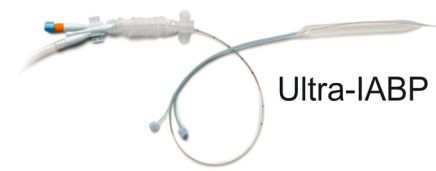
European Society of Cardiology (ESC)
recommends following through critical evaluation
& comprehensive review of published evidence:

IABP in first-line for cardiogenic shock.

Class IIb, evidence level B

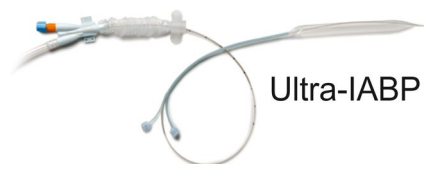
LVAD for circulatory support ONLY in patients in refractory shock Class IIb, level of evidence C

ESC Guidelines for management of AMI in patients presenting with ST-segment elevation. Ph. Gabriel Steg, et al. European Heart Journal. 2012



Benefits of 7Fr Technology

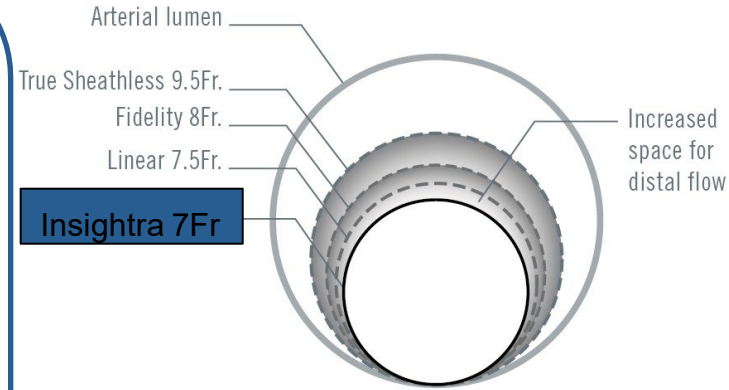
True 7Fr Technology



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

True 7Fr has major patent 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

8Fr performance in a 7Fr device



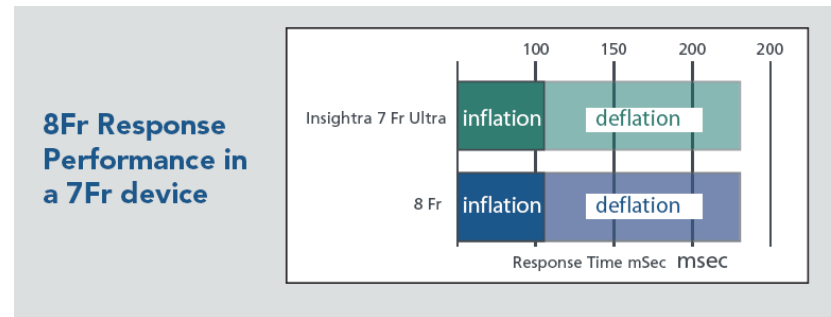
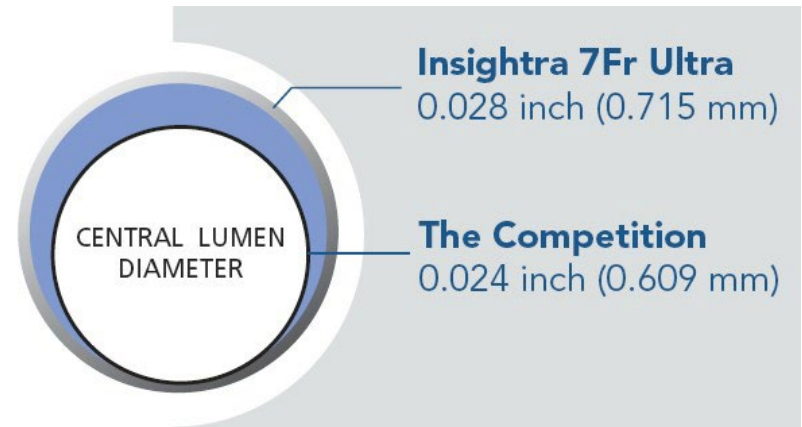
- Reducing size **MUST** not reduce performance
- Unique V-Hub – crucial feature – allows comparative inflation - deflation response time as in an 8Fr device*
- This design (achieved through proprietary manufacturing) - allows for optimal gas shuttling and thus no loss in performance



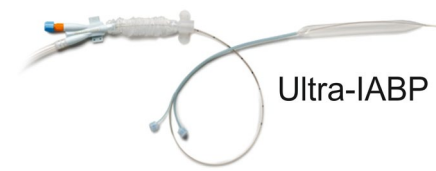
V-Shaped hub is the key to a high pulse rate in a 7Fr design



- 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.



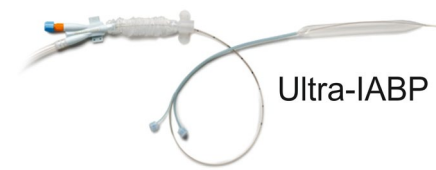
*Was compared to 8Fr Datascope balloon in clinical tests



Ultra-IABP

The Insightra Ultra 7Fr IAB Catheter Product Overview

Just Got Better...



Ultra-IABP

FLOWSTREAM

EXOSHEATH

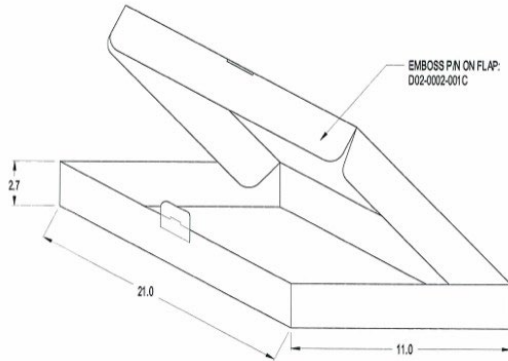
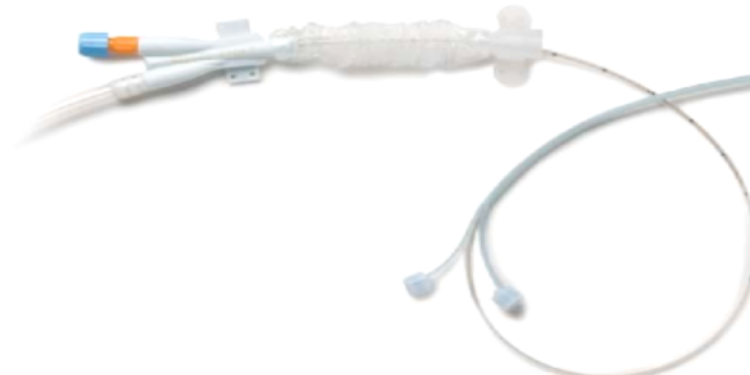
FLEXTIP

ADVATHANE

HINGEPACK

NANOCATH

IAB-SUPERWIRE



Compatibility

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

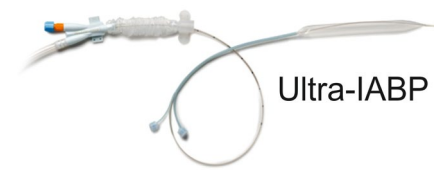
Balloon used >15 years on both consoles with no problems (balloon or console)

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

Compatibility

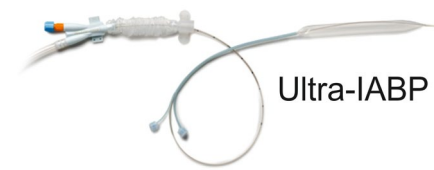


Ultra-IABP

The ONLY 7Fr balloon compatible with old & new machines!

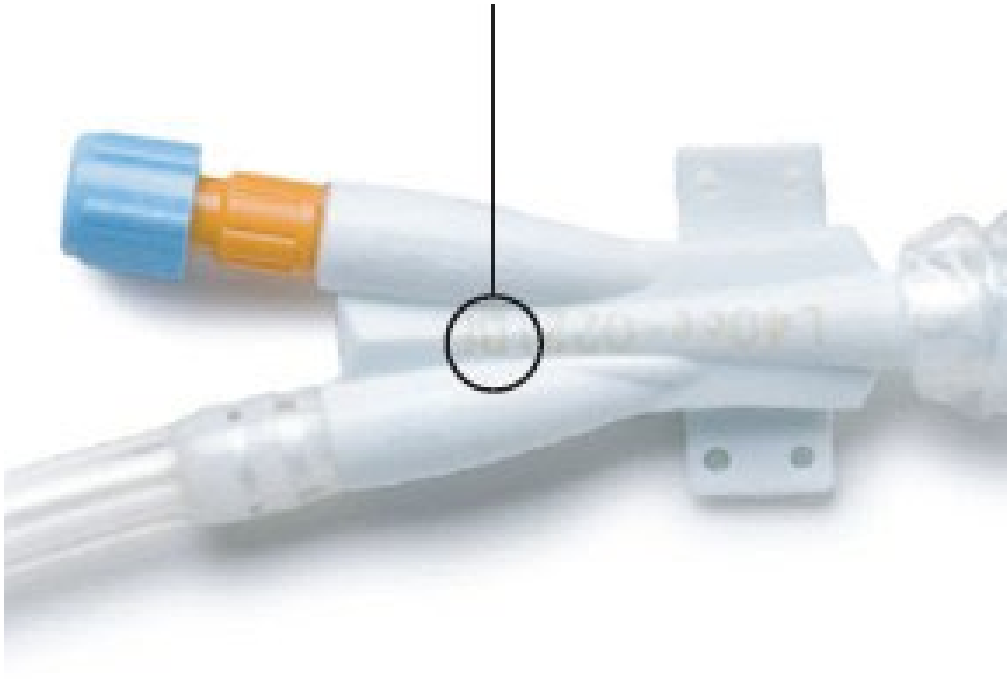
Datascope	Arrow
CS100, CS300, System 97, 98, 98XT, Cardiosave IABP Hybrid	ACAT, AutoCat, AutoCat2, AutoCat2 Wave, KAAT II, Autocat 3, AC3 Optimus

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



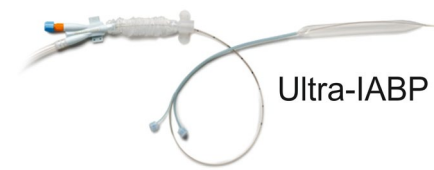
FLOWSTREAM

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

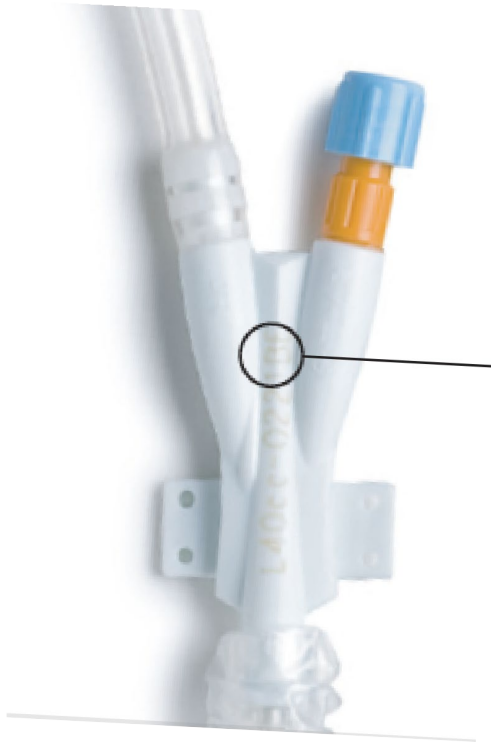


Gas flow is everything

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.

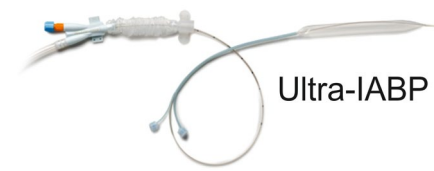
V-Hub is crucial in allowing fast – smooth flow.



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



IAB-SUPERWIRE

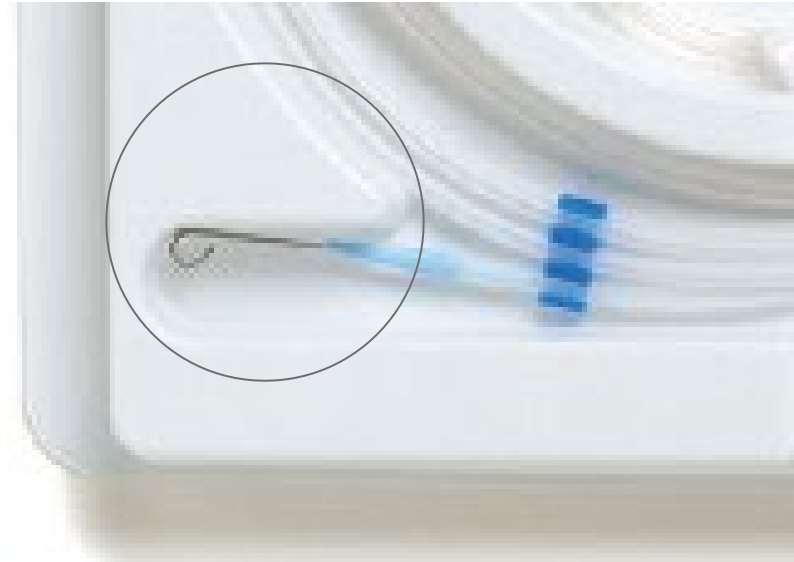
– Guidewire

Guide with confidence

Custom made guidewire only for the Inshightra IAB.

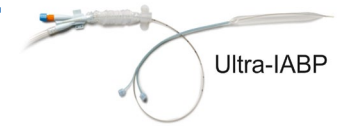
0.025" size with the soft J-Tip but improved rigidity. Wire wound PTFE coated technology

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



EXOSHEATH

Peel Sheath Introducer



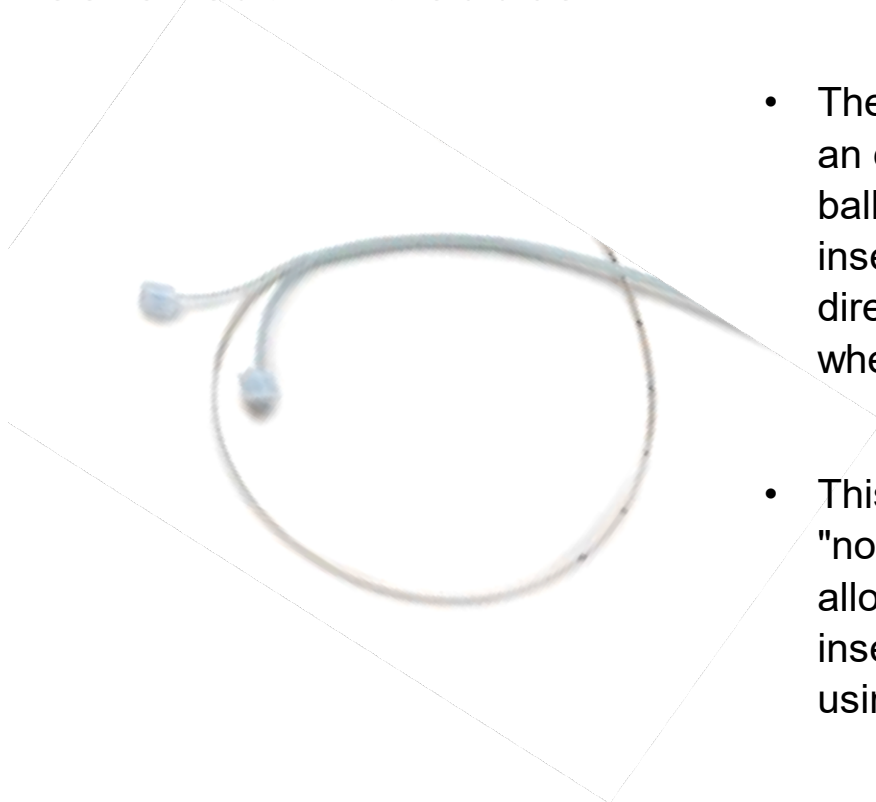
Introduce with confidence

- **External Stiffening Technology:**
 - Prevents internal balloon damage
 - Enables balloon stiffening in areas inaccessible to stylets
 - Employs a "no touch" technique
 - Unique design peels away effortlessly after both sheathed and sheathless insertions



EXOSHEATH

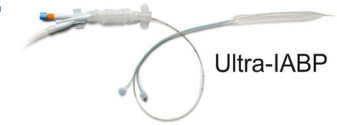
Peel Sheath Introducer



- The Exosheath functions as an exoskeleton for the balloon, facilitating easy insertion into the sheath or directly at the puncture site when used without a sheath.
- This can also be described as "no-touch" technology, as it allows the balloon to be inserted without direct contact, using the sheath for guidance.

EXOSHEATH

Peel Sheath Introducer



Advantage

- The primary advantage of using the Exosheath is that it allows for easier maneuvering of the IABP balloons, which are typically longer than coronary balloons, into the insertion site. IAB catheters are occasionally prone to kinking; however, Insightra's IAB kit uniquely provides this additional protective tool. The Exosheath offers extra support to the balloon, significantly reducing the risk of kinking.



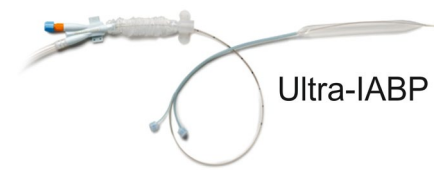
EXOSHEATH

Peel Sheath Introducer



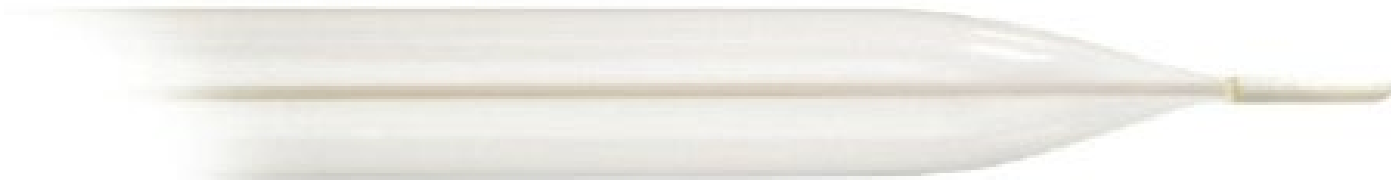
How to use

- Upon removal of the protective sheath, the secondary peel-away sheath can be advanced over the balloon up to its proximal tip. Once the tip is positioned within the sheath or at the puncture site, the peel-away sheath should be retracted while simultaneously advancing the balloon. This process should be repeated for three to four strokes. Once the balloon is fully advanced, the peel-away sheath can be slid onto the catheter and subsequently removed.



ADVATHANE

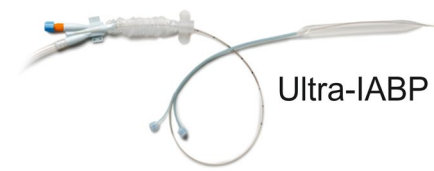
– Membrane Technology



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.



Trade secret manufacturing

- Balloon @heart of Inshitra catheter is UNIQUE
- Through a trade secret manufacturing process the Inshitra balloon (polyurethane) is molded with an ultra smooth surface texture with low defects. This gives major advantages:
 - Low thrombogenic activation due to the smooth physical surface
 - Highly durable balloon due to minimal defects
- Another secret is in the folding manufacture process. This allows a full volume 40cc balloon to be folded down on a full size shaft. Thus retaining 8Fr performance but with a 7Fr insertion profile
- Other trade secrets are incorporated into finishing, testing and design that make the Inshitra IAB catheter absolutely unique - providing superior performance

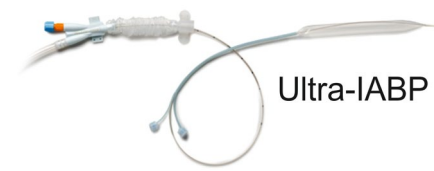


Ultra Smooth Balloon surface

Lowest rupture rate in a comparative clinical trial verses Datascope & Arrow (see clinicals)

Artificial Organs 1994 Nishida et al

10 years of experience



>15 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

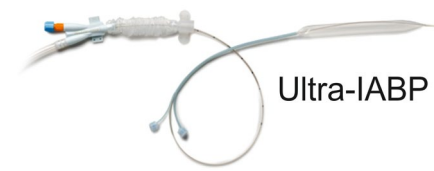
- Lowest @ 1%

ORIGINAL 7Fr balloon with proven technology

- 7Fr design years prior to any other company

Clinical experience

- Years more than any competitor device



Shelf Life

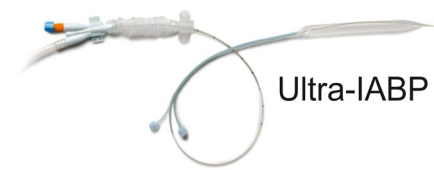
Ultra smooth Polyurethane & proprietary folding techniques gives smooth insertion to Inshightra IAB

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

ONLY Complete range



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

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

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

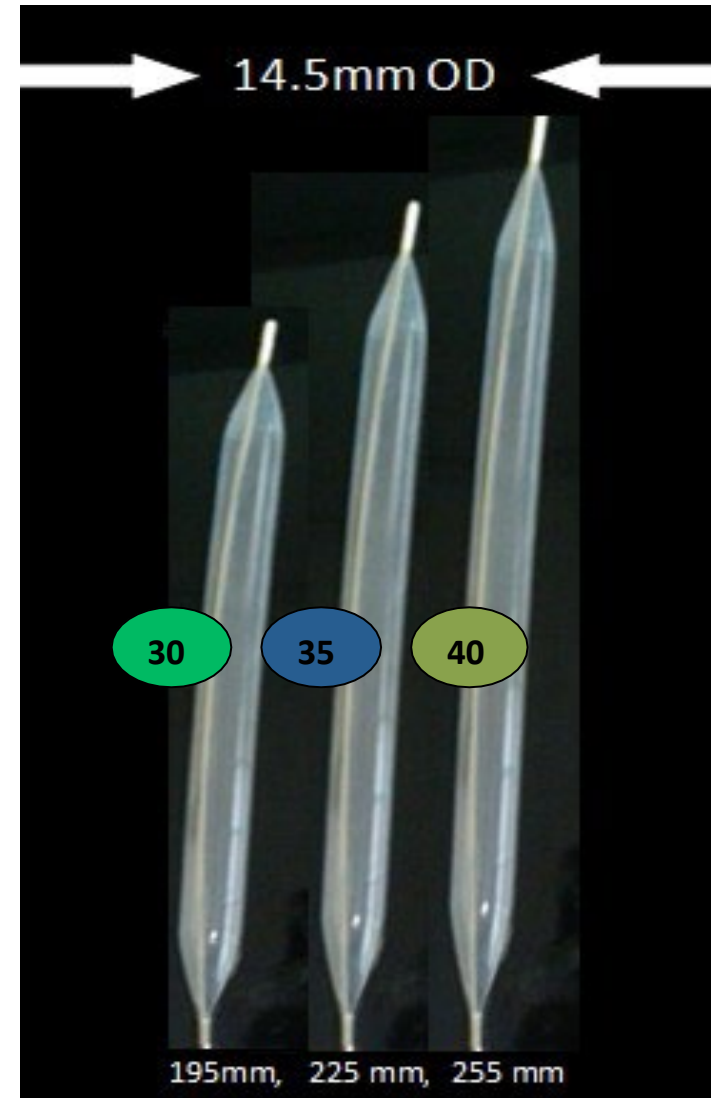
Tenders for 8Fr balloons are 8Fr and below (with 8Fr being the upper size limit). This complete range allows for Inshightra to compete in 9Fr, 8Fr and 7Fr tenders

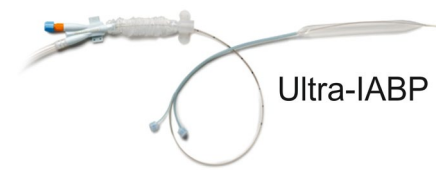
7Fr has major benefits and thus should be available to all patients

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!

Choose the Correct Size

- 14.5mm O.D.
- Wide length range from 195mm – 255mm
- Functionality remains the same matched to BSA

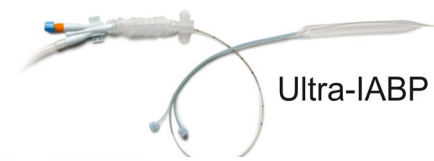




Ultra-IABP

The Ultra IABP Product Kit

Overview of contents



A: Accessory Tray

A



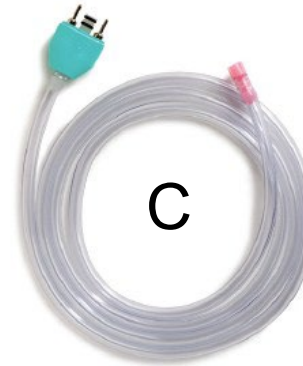
B: Main Tray

B



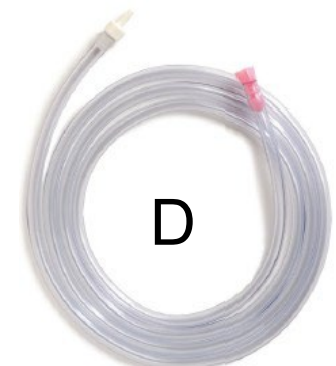
C: Arrow Adaptor

C

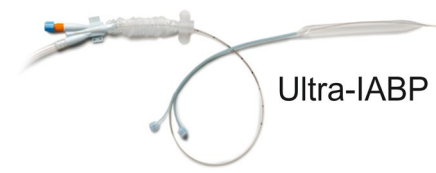


D: Datascope Adaptor

D



Accessory Tray



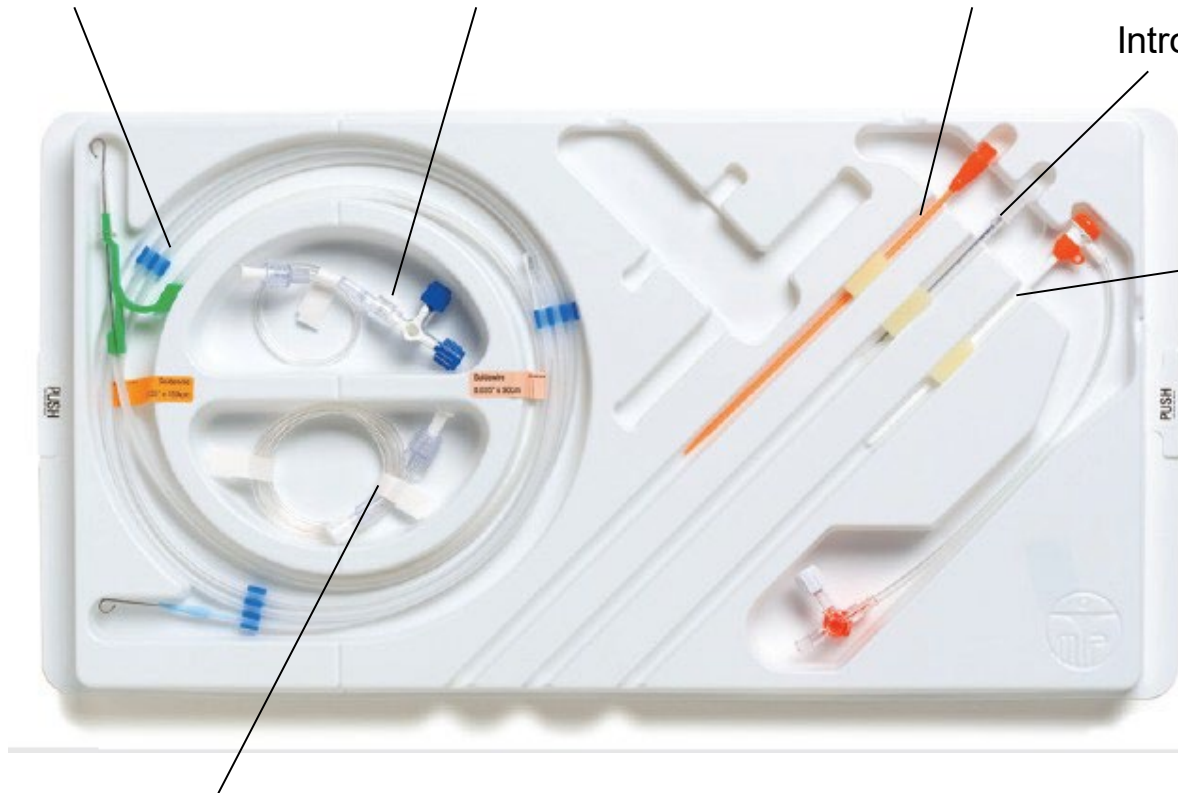
GuideWires (50cm & 150cm)

Stopcock

7Fr Dilator

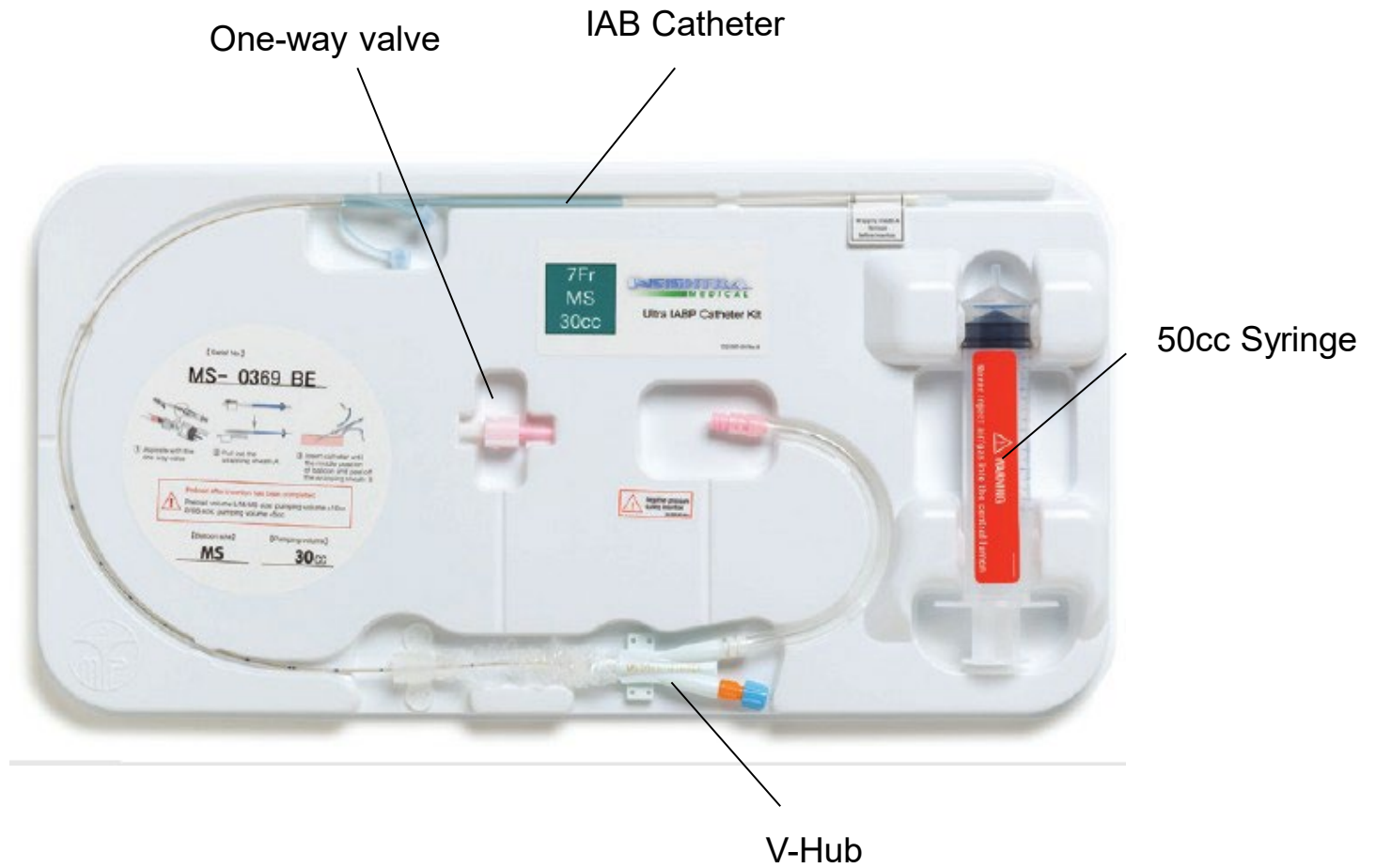
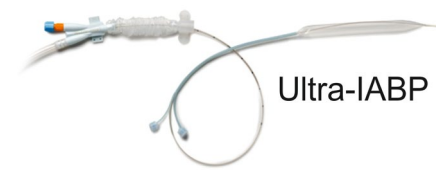
Introducer needle

7Fr Sheath

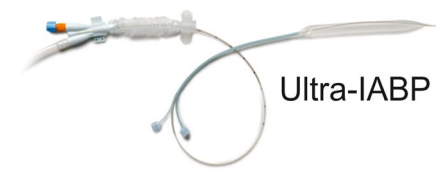


Pressure monitor tubing set

Main Tray



Product packaging



Ultra-IABP

- 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

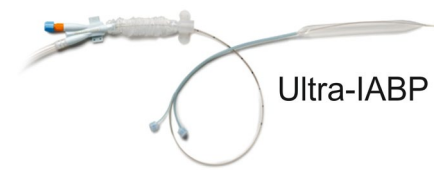
Class II device USA

Manufactured by Inshightra
Medical

ISO 13845:2016

Commercially available

English & Multi-Lingual
formats

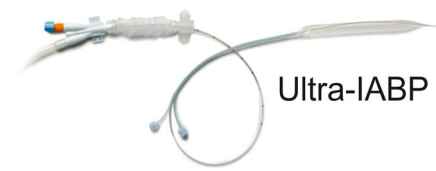


IAB Troubleshooting Summary

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 45° 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.

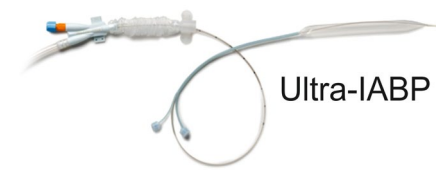


Instructions for How to Perform a Manual Fill

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



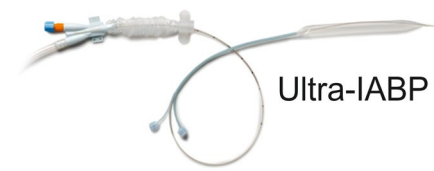
What is a Manual Fill



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.

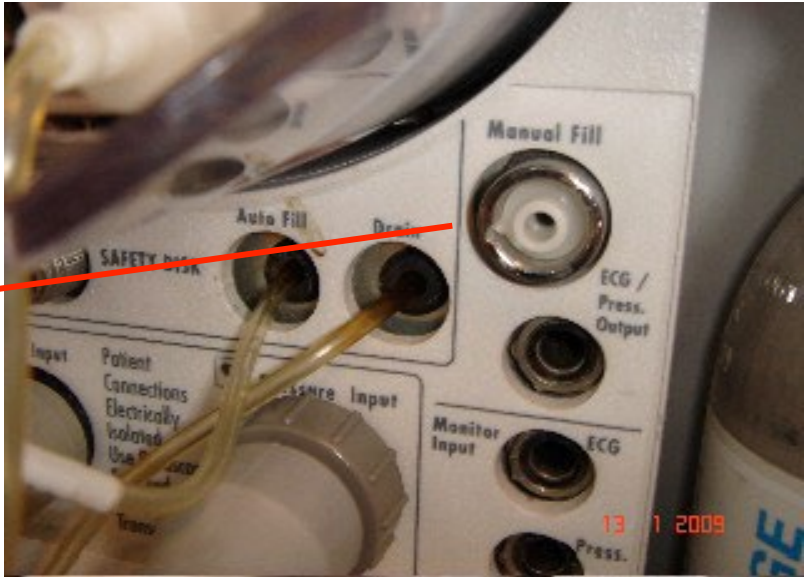
60cc syringe can be used to do this

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

Back of the IABP machine

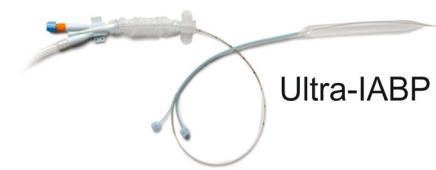


Ultra-IABP



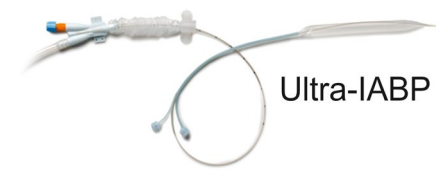
On the back of an IAB pump is a small “Manual Fill” valve

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



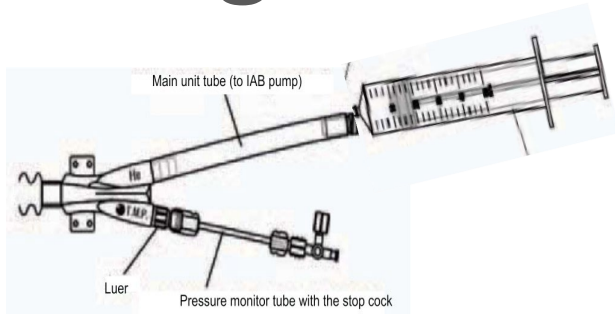
Draw the syringe plunger back to a maximum of 15cc to create a vacuum. This is enough to keep the balloon from unwrapping when inserting. Anything more than 15cc may cause damage to the balloon or may delay its unwrapping in the patient.

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

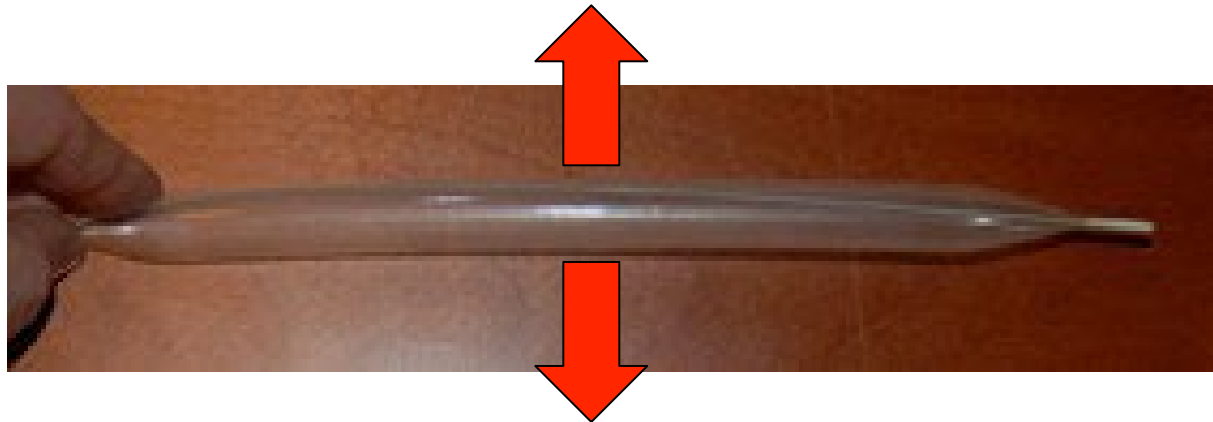
Pre-Inflating



Ultra-IABP



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



How Much Gas



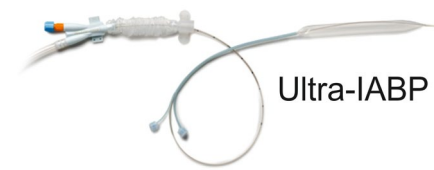
For 40cc & 35cc balloons, add the volume **plus 10cc**

- 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!

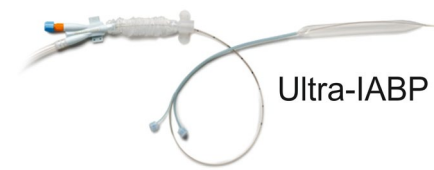


Although NOT mandatory - Manual filling has several advantages – especially in a 7Fr.

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.

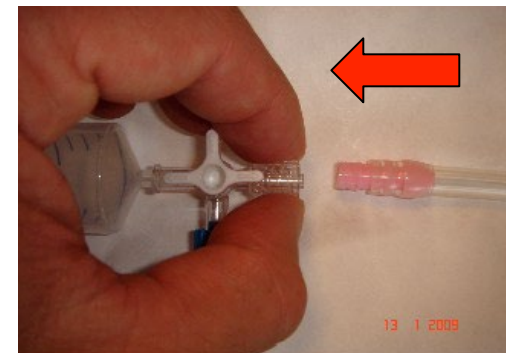
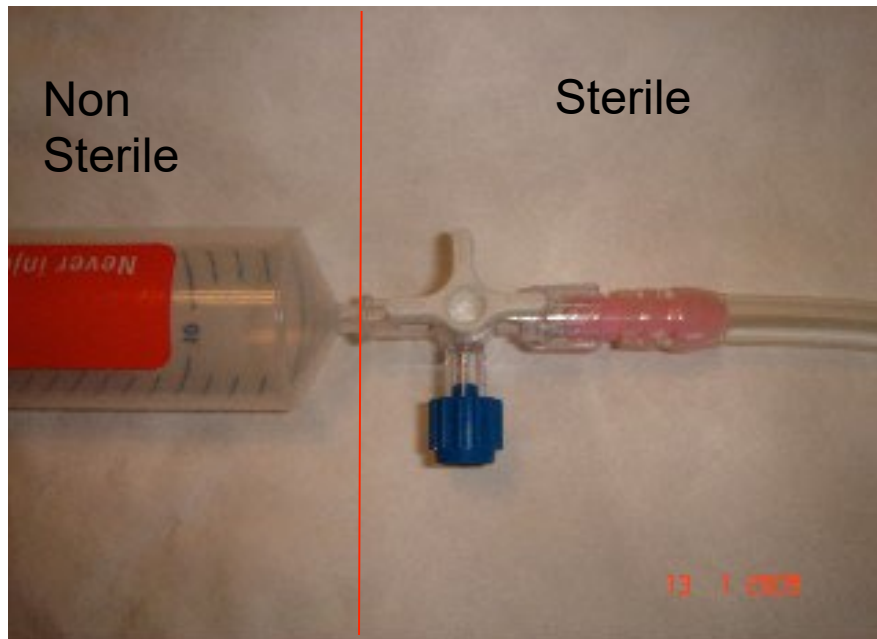


This series of steps has one problem – the syringe is no longer sterile!

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

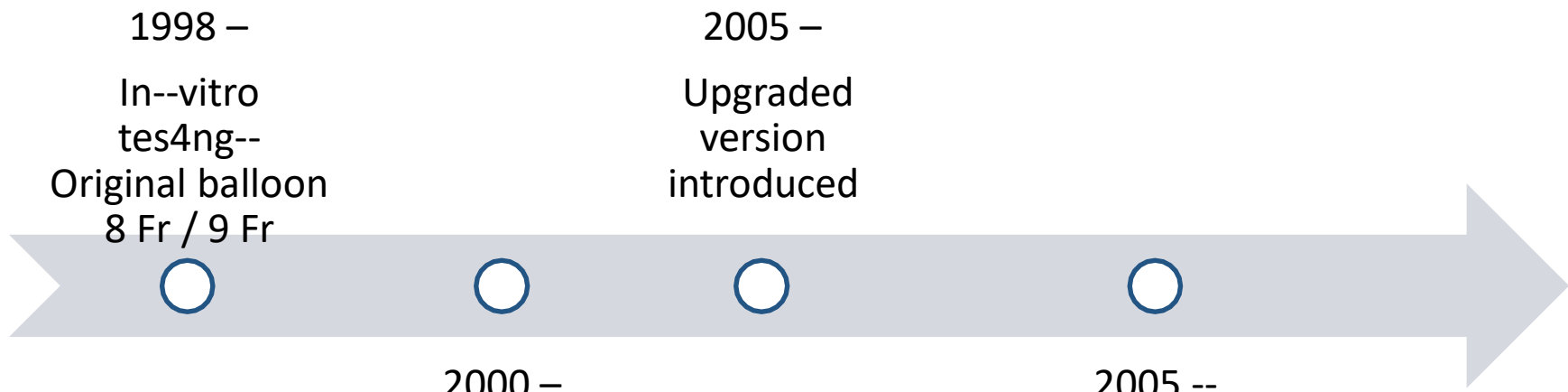
- Take the sterile 3-way stopcock
- And put it on the pink gas line adaptor
- Place the nonsterile syringe in the stopcock
- Inflate the balloon and withdraw the gas
- Remove the 3-way stopcock from the tubing
- The tubing remained sterile





Clinical & Market Evaluation Summaries

In Vitro Testing



Rigorous Tes4ng:

- Kink resistance,
- Balloon infla4on / defla4on,
- Pumping performance,
- wrapping diameter,
- unwrapping capability,
- inser4on resistance,
- bend fa4gue,
- joint strength,
- shelf life



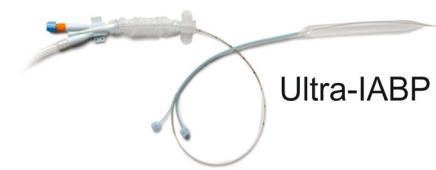
Clinical Tes4ng:

- at worst case limits



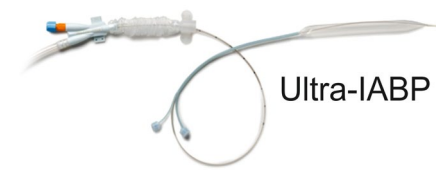
ALL TESTS PASSED

Market evaluation of 7Fr



- Market evaluation of 7Fr IAB was conducted in 2005 to verify product performance
- 50Pts at 14 hospitals using 6 different IAB Pumping systems
(Datascope: System 97, 98, CS100, ZEON: Console 907, Arrow: ACATI and KAATII)
- Summary: User feedback was positive: Improved distal flushing, easier blood withdrawal through central Lumen, improved pressure monitoring, worked with 0.025" guidewire
- Has been used clinically in thousands of patients with a complaint rate of circa 1%**

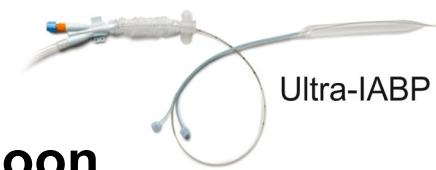
Clinical Evaluation (1)



- **Comparative Study of Five Types of IABP balloons in terms of incidence of balloon rupture and other complications: A multi-institutional study**
Nishida et al : Artificial organs 18(10) 746-751 1994
- 1988 - 1992 (9Fr with equivalent components to 7Fr)
- 2,876 patients, 14 hospitals in Japan
- Looking at catheter related complications
- Results

Manufacturer					
Complication	Insightra	KONTRON	DATASCOPE	BOST.SCI	ST.JUDE
Balloon rupture	0	15	20	3	11
Other	26	41	9	6	7
Total %	26(2.7%)	56(5.9%)	29(6.0%)	9 (4.0%)	18 (9.6%)

Clinical Evaluation (2)



- **Clinical use evaluation of the Insightra 7Fr IABP balloon catheter**

Matsuda et al Jan 2001 - May 2005

- 280 patients compared with Insightra 7Fr to 8Fr (Datascope, Zeon, TMP) First published - Cardioangiology 2002;51:465–466. 23
- Evaluated: Percutaneous insertion and maintain position, antiarrhythmia responsiveness, pumping performance, anti-ischemic effects and compatibility with Datascope and Arrow IAB pumps.
- Results:
 - Insightra 7Fr balloon had the lowest insertion resistance
 - All products stayed in position with maximal change of 4mm
 - Patients with Ventricular tachyarrhythmia (VT) and Afib were examined for antiarrhythmia responsiveness. All products comparable
 - Anti-ischemia. No reports of lower limb ischemia with the 7Fr
 - Two cases of thrombus formation - Not with the Insightra product
 - 7Fr worked well with both Datascope & Arrow pumps and compared to the Datascope 8Fr Catheter performance (Pressure plateaus and inflation/deflation time were in-line with the 8Fr catheters)
 - Pressure monitoring was equally as good
- **Summary: 7Fr balloon performed as well as the 8Fr balloons (all manufacturers) in terms of performance, but were easier to insert**



Prolonged Use for at Least 10 Days of Intraaortic Balloon Pumping (IABP) for Heart Failure

Kiyohiro OSHIMA,^{1,2} MD, Yasuo MORISHITA,¹ MD, Hiroshi HINOHARA,² MD, Yuji KADOI,² MD, Yoshiro HAYASHI,² MD, Yukio TAJIMA,³ ME, and Fumio KUNIMOTO,² MD

Intl Heart J Vol46 No 6 November 2005

- 18 patients underwent extended (10 day) therapy using the 7Fr IABP
- No reports of balloon rupture even at extended use
- Proves 7Fr is a reliable balloon

Thank You