# Intra Aortic Balloon Catheter Kit Instructions For Use

INSIGHTRA®
MEDICAL

D02-0161-001 Rev G

**ENGLISH**

# Ultra - IABP 7 Fr

Intra Aortic Balloon Catheter Kit Instructions For Use

## Product Description

The intra aortic balloon (IAB) catheter is used for emergency mechanical left heart assist in conjunction with an IAB catheter pumping system.

The balloon is appropriately placed in the aorta, and is subsequently inflated and deflated based on synchronization to the electrocardiogram or arterial pressure. When the balloon is inflated in the cardiac diastolic phase, the blood flow into coronary arteries is increased, leading to increased oxygen supply to the myocardium. Conversely, when the balloon is deflated in the cardiac systolic phase, the after-load is reduced, and the workload of the myocardium is reduced, decreasing the oxygen requirement of the myocardium. The overall cardiac function is enhanced by this combined increase in perfusion and reduction of workload.

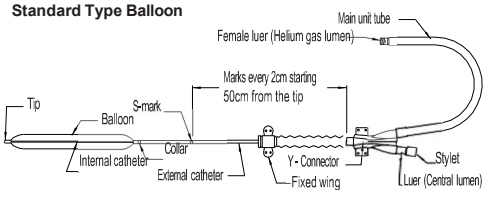
## Ultra IABP 7Fr Specifications

| MODEL | IMU7F-40 | IMU7F-35 | IMU7F-30 | IMU7F-25 | IMU7F-20 |
|---|---|---|---|---|---|
| BALLOON SIZE | L | M | MS | S | SS |
| VOLUMETRIC CAPACITY | 40CC | 35CC | 30CC | 25CC | 20CC |
| PATIENT HEIGHT | >165 cm | 165-155cm | 155-145cm | <145cm | |
| TOTAL BALLOON LENGTH | 255mm | 225mm | 195mm | 180mm | 170mm |
| BALLOON OUTER DIAMETER | 14.5mm | | | 13.5mm | |
| CATHETER DIAMETER | 7Fr | | | | |
| COMPATIBLE GUIDE WIRE | 0.025 inch | | | | |
| CENTRAL LUMEN DIAMETER | 0.028 inch | | | | |
| EFFECTIVE LENGTH | 700mm | | | | |
| DILATING PRESSURE-NOMINAL | 19.5 kPa | | | | |
| DILATING PRESSURE-MAXIMUM | 29.25kPa | | | | |
| MINIMUM JOINT STRENGTH | 5N | | | | |

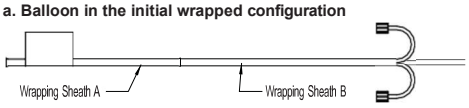
## Components and Assemblies

Intra Aortic Balloon (IAB) Catheter

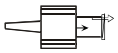
**Standard Type Balloon**



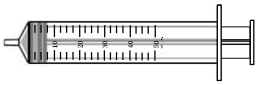

**a. Balloon in the initial wrapped configuration**



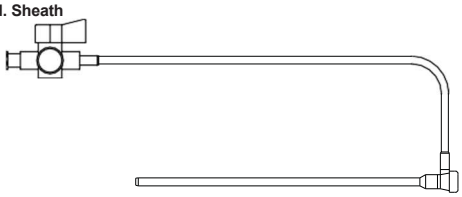

**b. One-way valve**



**c. 60cc Syringe**

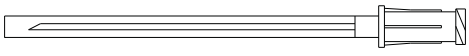


**d. Sheath**

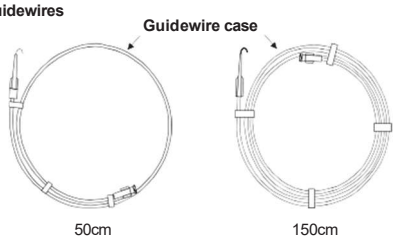


**e. Dilator**

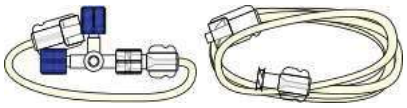
**f. Introducer needle**



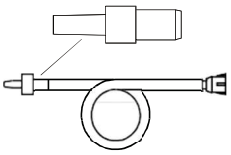
**g. Guidewires**



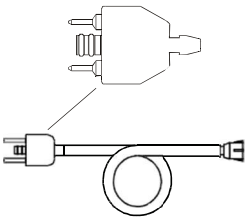

**h. Pressure monitor tubing with stop cock**



**i. Datascope® type extension tube with adaptor**



**j. Arrow® type extension tube with adaptor**



**Note:** The Arrow type IABP extension tube with adaptor is not supplied with the model IMU7F-20 IAB catheter kit.

**Note:** All components in the IAB catheter kit are latex free.

**Caution:** The connector for the pump and extension tube are already connected before packaging.

## 1. Indications for use

The Insightra Intra Aortic Balloon Catheter Kit has the following indications for use:

A. Refractory Unstable Angina.
B. Impending Infarction.
C. Post infarction angina.
D. Refractory left ventricular failure.
E. Complications of Acute MI (ie. Acute MR or VSD or papillary muscle rupture).
F. Cardiogenic shock.
G. Support for diagnostic, percutaneous revascularization and interventional procedures.
H. Ischemic related intractable ventricular arrythmias.
I. Septic shock.
J. Intraoperative pulsatile flow generation.
K. Weaning from cardiopulmonary bypass.
L. Cardiac support for non-cardiac surgery.
M. Prophylactic support in preparation for cardiac surgery.
N. Post-surgical myocardial dysfunction/low cardiac output syndrome.
O. Cardiac contusion.
P. Mechanical bridge to other assist devices.
Q. Cardiac support following correction of anatomical defects.

## Contraindications

1. Patients with serious aortic insufficiency. Blood may reverse into the left ventricle of the heart during balloon dilation, exacerbating cardiac failure due to increased left heart preload.
2. Patients with chest or abdominal aortic aneurysm. Damage to the aorta may occur during insertion, dilation, or removal of the balloon.
3. Patients with serious vascular tortuosity or calcification of the aorta, iliac or femoral artery. Damage to the vasculature may occur. Risk of damage to the catheter could be expected.
4. Patients with lesions in the peripheral blood vessels.Hemodynamic complications in the lower extremities may occur.
5. Patients with serious abnormal blood coagulation. Difficulty in achieving hemostasis, thrombosis, or embolism might occur.

## WARNINGS

- Use of this product is restricted to clinicians who are trained and experienced in the use of IAB catheters and IAB pumping with Datascope or Arrow pumps.
- Product intended for single use only. Do not resterilize.
- Reuse, reprocessing or resterilization may compromise the structural integrity of the device causing device failure and/or lead to patient infection or cross infection which in turn may result in patient injury, illness or death.
- Do not infuse air into the central lumen (luer). Gas embolization might occur, leading to organ damage. While infusing contrast media through the central lumen (luer), do not use an injector designed for angiography. If excessive pressure is applied, the central lumen could be damaged.
- Promptly remove any balloon catheter that develops a leak, prior to initiating pumping. Organ damage may occur due to gas embolization, or blood clots may form within the balloon, making it difficult to remove.
- If balloon leakage or catheter damage is suspected, do not dilate the balloon in any manner. Multiple infarctions due to gas leakage into the descending aorta may occur.
- When inserting the balloon catheter, do not apply excessive force. Damage or tearing of the blood vessel may occur, or the balloon itself could be damaged.
- If resistance to catheter movement is identified, or an abnormal bend is found in the balloon, or a bend is present in the internal catheter, immediately change the position of the balloon. If it is left in place, the duration of balloon life could be shortened, resulting in a leak or fatigue failure of the internal catheter.
- Do not utilize the product when any portion of the balloon is bent due to tortuous blood vessels or an inappropriate placement. Leaking may occur due to material fatigue.
- If blood is found in the helium gas lumen, immediately remove the balloon catheter. The balloon may have been damaged during the insertion procedure.
- Never use a balloon if any resistance is felt within the central lumen. The central lumen may be occluded.
- Always insert the balloon catheter by passing the guidewire through the central lumen. Incorrect balloon placement may result or the catheter could perforate the arteries.
- If problems occur while attempting sheathless insertion, pull out the balloon catheter, and proceed with insertion using an accessory sheath. Damage to the blood vessels could occur.
- In the case of insertion with a sheath, do not remove the catheter alone. The sheath and catheter must be removed as a unit. The balloon may be damaged causing a portion of the balloon to become dislodged and remain behind in the artery.
- Do not attempt to remove any catheter whose internal lumen is ruptured using ordinary percutaneous techniques. The ruptured portion could perforate the balloon, or damage the blood vessel or surrounding tissue.
- Do not continue pumping a ruptured catheter. The blood vessel could be damaged by the ruptured catheter, or organ damage could occur due to gas embolization.
- During catheter insertion, utilize fluoroscopy to observe placement when possible to confirm final catheter position. If the catheter is not inserted under live fluoroscopy, then confirm its final position fluoroscopically as soon as possible.
- The IAB catheter should not remain inactive (i.e., not inflating or deflating) for more than 30 minutes because of the potential for thrombus formation.
- This product is not intended for long term use or permanent implantation. There could be risk of thrombosis, embolism, organ damage or death.

## Precautions

**1. General cautions**

- During insertion, hold the part of the balloon catheter closest to the puncture site, and advance slowly, particularly with patients who have severely tortuous vasculature. Otherwise kinking may occur.
- During pumping of the balloon catheter, regularly confirm the movement of the catheter or the state of the balloon. In particular, if abnormal blood pressure wave forms or pumping pressure wave forms are found, confirm fluoroscopically the condition of the balloon catheter. If the tip of the balloon catheter does not move, or a bend is found in any portion of the balloon, confirm whether the tip is captured by the vascular wall. If any abnormality is found, correct the position of the balloon placement. The tip of the balloon may contact the vascular wall during pumping and damage to the vasculature may occur.
- Regularly check the peripheral circulation to prevent hemodynamic complications in the lower extremities.
- Do not attempt sheathless insertion in patients with serious obesity, scarring in the inguinal region, or contraindicating symptoms for percutaneous insertion. Damage to the balloon catheter or the vasculature may occur.
- Determine the effectiveness of intra aortic balloon pumping (IABP) treatment based on an increase in cardiac index, reduction in pulmonary artery wedge pressure, and increase in urinary output, taking appropriate clinical measures for changes in patient condition.
- During use, regularly confirm for breakage of the four-way stop cock, loosening of the junction, or leakage of blood or other fluids.
- In the case of administering fat emulsion or drugs containing fat emulsion, fat ingredients such as castor oil, or drugs containing solubilizing agents such as surface acting agents or alcohol, as well as in the case of use of disinfectants containing alcohol through the four-way stop cock, observe for evidence of cracking of the four-way stop cock and balloon catheter main unit. Drug solutions may cause cracking in the four-way stop cock or luer, which might cause blood and drug solution leakage, or aeration to occur. Retightening, or excessive tightening, at the time of line exchange may also promote the occurrence of cracking.
- If cracking is confirmed in the four-way stop cock, immediately exchange with a new one.
- When inserting the dilator into the sheath, insert aiming at the center of the hemostatic valve.
- If a hydrophilic coated guidewire is used, always flush the inside of the guidewire case with sterile physiological saline and sufficiently hydrate the wire. If not sufficiently hydrated, lubricity may not be obtained, and damage may occur at the time of removal from the guidewire case or at the time of insertion into the balloon catheter.
- Avoid the use of concentrated alcohol or organic solvents such as acetone in the vicinity of the balloon catheter or its accessories. Material deterioration may occur.
- Never infuse air into the pressure monitoring tube via the stop cock and luer. May cause air embolism.
- All air should be purged from the central lumen, four-way stop cock and pressure monitoring lines.
- Avoid instruments such as scalpels or introducer needles in the vicinity of the balloon catheter and its accessories. Damage might occur.
- If the blood pressure of the patient is high or the balloon is not completely dilated an alarm may occur. It is preferable to pump against reduced blood pressure by introducing hypotensive drugs. In this case, refer to the instruction manual of the IAB pump, and pump by slightly lowering the pumping volume of the balloon until the blood pressure of the patient is reduced. Immediately after the blood pressure is lowered, restore to the regular pumping volume.
- If an alarm message of the IAB pump appears, or the alarm beeps, refer to the instruction manual of the pump.
- If the patient with the balloon catheter inserted is transferred between hospitals, confirm the type of pump in the hospital where the patient is to be transferred. If there is no adaptor for the pump in the hospital where the patient is transferred, it is impossible to use the balloon catheter.
- If the catheter is used with balloon leakage, serious health hazards such as gas embolization (or helium embolization) might occur. In addition, any blood within the balloon may coagulate, and removal of the balloon catheter could become difficult. If the gas leak detection alarm occurs, confirm the cause of gas leak by the following procedure:

1. If a gas leakage detection alarm occurs, and blood is mixed in the helium gas line, then balloon leakage is suspected. Immediately remove the catheter without restarting pumping.
2. If blood is not mixed in the helium gas line, confirm initially whether there is a loosening or detachment of the connection to the helium gas line. If a loosening or disconnection is suspected connect the syringe to the female luer of the main unit tube, draw on the syringe, and confirm whether reflux of blood is found when a negative pressure state is produced within the gas lumen. If blood is confirmed, immediately stop pumping and remove the balloon catheter. If no blood is found, reconnect the helium gas line to the female luer of the main unit tube and resume pumping.
3. If the catheter shaft or extension tube is kinked then straighten or remove the kink.
4. If there are any abnormal arterial pressure wave forms or internal balloon pressure variations after pumping is restarted, discontinue pumping and remove the IAB catheter.
5. If the gas leak detection alarm sounds again after IAB pumping is restarted, do not continue pumping, and repeat status checks 1 through 3 above. If there is no abnormality in the catheter after reconfirmation, consider exchanging the pump.

**2. Failure/adverse events**

From the use of this product, the following failures or adverse events may occur:

**(1) Serious failures**

Perforation of the balloon catheter, or shaft may occur during pumping.

**Reasons for occurrence**

- Contact with sharp instruments
- Material fatigue due to abnormal bending
- Abrasion damage due to contact with any calcification

**Time to failure**

Failure due to contact with calcification, or material fatigue can occur at any time during the use of the device.

**Recommended preventive measures**

Frequently check the main unit tube and helium gas line for reflux of blood in the lumen. If blood is observed, immediately remove the balloon catheter. However, in the case of a small perforation in the early stage, presence of blood may not be easily observed, thus pay particular attention to pump alarms.

**Recommended actions**

If perforation occurs, or it is suspected, immediately take the following measures.

1. Stop pumping the balloon. Consider reduction or discontinuation of the anticoagulation therapy.
2. Remove the balloon catheter from the patient in accordance with “Removal of balloon catheter” described in these instructions for use.
3. If it is necessary to continue IAB pumping treatment after removing the balloon catheter, utilize the opposite femoral artery for insertion. In addition, if the perforation in the balloon is associated with the vascular state of the patient, recurrence might be expected.

**(2) Serious adverse events**

Ischemia in the lower extremity on the insertion side.

Ischemia symptoms in the extremities might occur during or after pumping of the balloon catheter.

**Reason for occurrence**

Blood flow could be blocked by thrombus formation, detachment of an endothelial tissue flap, introducer size, or the balloon catheter itself.

**Time to occurrence**

It may occur immediately after insertion of the balloon catheter or post removal depending on the vascular state of the patient.

**Recommended preventive measures**

Regularly check the peripheral circulation from the start of pumping and throughout the procedure. In particular, post removal, frequently confirm the pulse on the peripheral side of the puncture site. The following patient types may be at higher risk of ischemia:

1. Patients with a small body frame, and patients whose blood vessel diameter is expected to be small.
2. Patients with active movement during treatment.
3. Patients with coagulation abnormalities.

**Recommended actions**

If the occurrence of ischemic symptoms are confirmed during pumping, remove the balloon catheter. After removal of the balloon catheter, if an ischemic state persists, consider surgical corrective measures.

**Damage/dissection or perforation of the aorta**

At the time of insertion of the sheath, guidewire, or balloon catheter, perforation or dissection of the arterial wall could occur.

**Reason for occurrence**

Damage from insertion of the sheath, guidewire, or balloon catheter.

**Time to occurrence**

It normally occurs at the time of insertion.

**Recommended preventive measures**

If resistance is felt during insertion of the balloon catheter, discontinue insertion. If the following symptoms are observed, take appropriate measures at an early stage, which may reduce the possibility of developing serious health hazards.

1. Pain in the back or abdomen.
2. Decreased hematocrit value.
3. Destabilization of hemodynamics.

**Recommended actions**

If damage or perforation of the aorta is confirmed or suspected, remove the balloon catheter. If it is suspected the balloon catheter has not been placed in the desired vessel, fluoroscopically infuse a small amount of contrast media into the central lumen of the balloon catheter and observe how the contrast medium dissipates from the tip of the balloon. If the shadow caused by the contrast media is not scattered from the tip of the balloon with the heartbeat, but remains localized, the balloon could be located within the wrong vessel. In this case, remove the balloon catheter, and try to insert again from the opposite side femoral artery.

**(3) Other adverse events**

**3.1 Bleeding at the insertion site.**

Bleeding from the insertion site of the femoral artery or hematoma formation in subcutaneous tissue near the insertion site may occur.

**Reason for occurrence**

- Damage to the arteries during insertion of the balloon catheter.
- Excessive movement of the balloon catheter due to the change of the posture of the patient.
- Administration of anticoagulant.

**Recommended actions**

Maintaining peripheral blood flow, directly compress the puncture site and arrest bleeding. If it is difficult to arrest bleeding, take surgical measures.

**3.2 Infection**

**Reason for occurrence**

Infection may occur because the skin around the insertion site fails to maintain its proper defensive mechanisms.

**Recommended actions**

If infection is observed, take appropriate measures according to standard hospital procedure.

**3.3 Thrombocytopenia**
**Reason for occurrence**
Platelets may be damaged due to movement of the balloon catheter relative to the vasculature.
**Recommended actions**
Monitor platelet count, and supplement platelets if necessary.
**3.4 Thrombosis**
**Reason for occurrence**
Thrombosis may result from the foreign body reaction to the balloon catheter.
**Recommended actions**
Treatment differs depending on the range of the affected organs. Follow standard hospital practice based on the findings.
**3.5 False aneurysm at the insertion site after removal**
False aneurysm could occur at the insertion site after removal of the balloon catheter.
**Reason for occurrence**
- Damage to the arteries which occurs at the time of insertion/removal of the balloon catheter.
- Excessive movement of the balloon catheter caused by the change in the posture of the patient.

**Recommended action**
If false aneurysm is observed, use appropriate treatments according to standard hospital practices.

## Storage/preservation method and use periods
1. Storage/preservation method
Avoid exposure to water, direct sunlight, extreme high or low temperature or humidity.
2. Use period
A "Use by:" date is referenced on the label.

## Method or methods of use
- Do not use the product after its Use by date has passed.
- Do not use the product if any part of the packaging sterile barrier has been compromised.

## Size selection of balloon catheter
Determined by clinical judgment evaluating all relevant patient parameters such as body size, vascular condition, etc. Refer to Ultra IABP 7Fr specifications as a guideline.

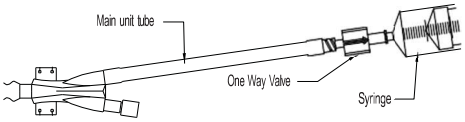
## Equipment required
1. Equipment required for insertion
- Balloon pump drive unit for assisted intra aortic circulation
- Topical anesthetics
- Heparinized sterile physiological saline
- 10cc-20cc syringe
- Scalpel for incision
- Drape
- Suture with the needle

2. Equipment and materials necessary for removal
- Four-way stop cock
- 60cc Syringe

## Procedure for balloon catheter insertion
1. Using sterile technique, remove the main tray (containing the IAB catheter) from the sterile pouch.

**Caution:** If there is evidence that the product or its packaging is damaged, or moisture is found in the package, do not proceed with use.
2. Remove the main unit tube portion from the tray.
3. Attach the one-way valve to the main unit tube.
4. Attach the 60cc syringe to the one-way valve connected to the main unit tube.

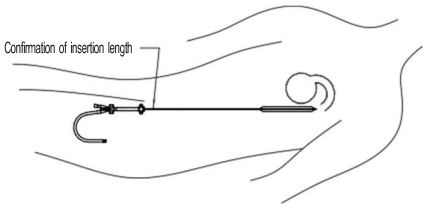
**Caution:** Carefully attach the syringe to the one-way valve. Do not apply force to the syringe in the lateral direction during use. Kinking or cracking of the syringe junction might occur.




5. Draw the syringe slowly so that negative pressure is produced within the balloon.

**Note:** When taking the balloon catheter out of the tray, maintain the negative pressure within the balloon.
**Caution:** Avoid producing excessive negative pressure, this may cause deformation of the catheter. Do not withdraw more than 15cc of air.
6. Detach the syringe from the one-way valve, maintaining the connection between the one-way valve and main unit tube.
7. Picking up the Y-connector portion, slowly take the balloon catheter out of the tray.
8. Confirm the insertable length by placing the tip of the balloon catheter at the estimated level of the patient's left subclavian artery, then extend the proximal end of the catheter to the insertion site. Ensure that there is sufficient insertion length.

**Caution:** Do not allow the balloon to touch the patient or it will become non sterile.
**Note:** There are markers every 2cm in the range of 50cm- 70cm from the proximal end of the balloon.

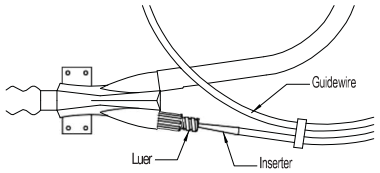



9. Remove the stylet from the central lumen luer of the balloon catheter.

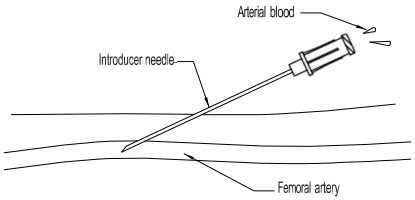
**Caution:** Do not attempt to re-insert the stylet once it is removed.
**Note:** If a Teflon-coated guidewire is used, proceed to step 11.
10. If a cover is placed on the tip of a hydrophilic coated guidewire, remove the cover. Flush the inside of the guidewire case with sterile physiological saline to appropriately moisturize the whole guidewire, and slowly remove the guidewire.

**Caution:** If not appropriately hydrated, the guidewire may not be lubricated adequately, resistance to guidewire insertion could be encountered resulting in damage or breakage.

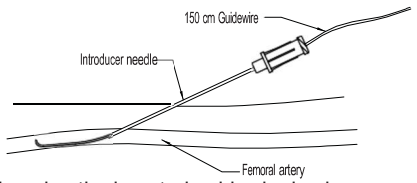
11. In the case of insertion using the sheath, put the 150cm guidewire through the luer of the balloon catheter into the central lumen.



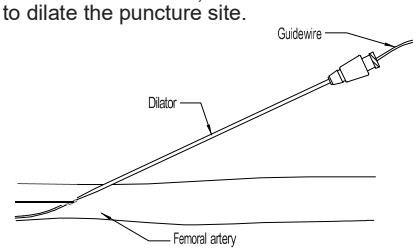

## Access/Dilation
1. Confirm the position of the femoral artery.
2. Prepare to insert the catheter by standard percutaneous techniques, and apply the appropriate local anesthesia.
3. Incise the puncture site in the skin using a scalpel.
4. Puncture the femoral artery using the introducer needle inserted at a 45 degree or less angle.
5. Pull back slowly on the introducer needle until arterial blood flow is confirmed.




6. In the case of placement using the sheath, insert the tip of the 50cm guidewire through the introducer needle. In the case of placement without using the sheath, insert the tip of the 150cm guidewire through the introducer needle.




7. Leaving the inserted guidewire in place, remove the introducer needle.
8. Insert the dilator by back loading over the guidewire. Pass the dilator through the skin, subcutaneous tissue, and into the blood vessel to dilate the puncture site.

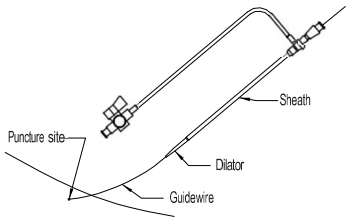



9. Remove the dilator, controlling bleeding from the puncture site with finger compression.

**Note:** In the case of sheathless insertion bypass the "Sheath insertion" steps and go directly to the "Balloon catheter insertion" steps.

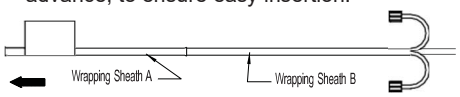
## Sheath insertion
1. Carefully insert the dilator into the hemostasis valve of the sheath.

**Caution:** When inserting the dilator through the hemostasis valve, ensure that the dilator passes directly through the center of the valve. Forcing the dilator off angle through the valve can cause damage and loss of hemostatic function
2. Place the pointed tip of the dilator together with the sheath over the guidewire which is inserted in the body, inserting the sheath and dilator into the blood vessel.



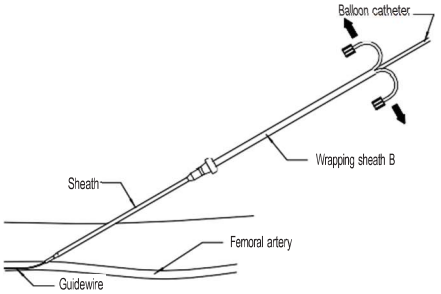

3. With the sheath in place, remove the dilator and guidewire.
4. It is recommended that anticoagulation be administered in accordance with standard hospital protocol.

## Balloon catheter insertion
1. Remove the wrapping sheath "A" by pulling in the direction towards the tip of the balloon catheter. Moisten the surface of the balloon with heparinized physiological saline in advance, to ensure easy insertion.

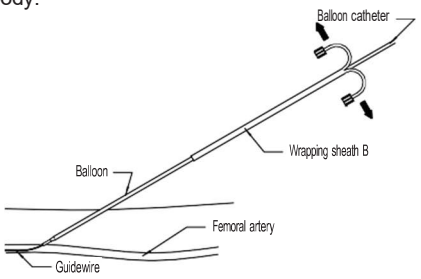



**Caution:** Do not remove the wrapping sheath A until immediately before insertion.
**Caution:** Do not remove the wrapping sheath B until the balloon is fully inserted into the introducer sheath or puncture site.
2. After removing wrapping sheath A slide wrapping sheath B to within 2cm of the tip of the balloon.
3. In the case of insertion using a sheath, slowly insert the tip of the balloon into the introducer sheath.

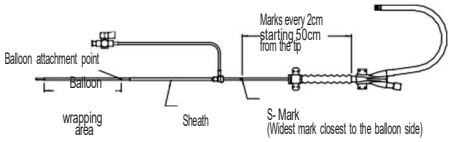
**Caution:** Advance the 150cm Guidewire in accordance with standard interventional techniques



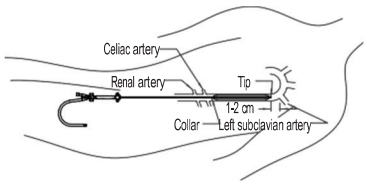

**Caution:** Do not use the balloon catheter if it is dilated prior to insertion.
**Caution:** If the balloon catheter does not pass easily through the sheath, there may be a bend in the sheath. In this case, pull back the sheath slightly outside of the body to relax the bend, and insert the balloon catheter.
**Caution:** During balloon insertion, bleeding may occur as a result of arterial pressure forcing blood along the folds of the balloon material. This phenomenon is called channeling, and is not abnormal. As the IAB catheter is being inserted, the outflow of the blood will be reduced.
**Note:** In the case of sheathless insertion, insert the tip of the balloon over the end of the guidewire, and slowly continue insertion into the body.




**Caution:** Do not use the balloon catheter if it is dilated prior to insertion.
4. Advance the balloon catheter in a stepwise fashion exerting pressure on wrapping sheath B to grip the balloon catheter. When wrapping sheath B reaches the insertion sheath or puncture site, relax the pressure and slide wrapping sheath B backwards 3cm. Repeat until the balloon is fully inserted.
5. Tear away the wrapping sheath “B”. There is an S-marker on the catheter body that is located 50cm from the tip of the catheter. There are marks every 2cm from this position that may be used for reference during insertion.

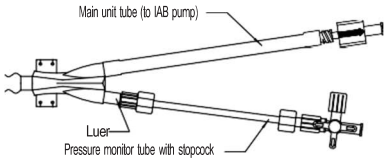



6. Place the balloon catheter, confirming fluoroscopically that the tip of the balloon is in the position about 1-2 cm below the opening to the left subclavian artery. (The tip and the collar are made of radiopaque material so that the position of the balloon can be confirmed).

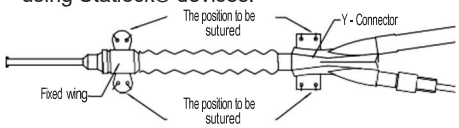



**Caution:** Place the balloon, taking care not to occlude the celiac artery or the renal artery.
**Caution:** In the case of placement without fluoroscopic control, confirm fluoroscopically the position of the balloon catheter as early as possible after placement using appropriate imaging technique.
7. In the case of insertion using a sheath, move the fixed wing to cover the hemostatic valve, and connect it to the sheath. In the case of sheathless insertion without a stopper, if bleeding occurs arrest bleeding by using standard hospital techniques.
8. Remove the guidewire from the balloon catheter.
9. Connect the pressure monitoring tube extension with stop cock to the central lumen luer. After allowing 5ml of blood to pass through the pressure monitor tube/stop cock assembly, sufficiently flush the catheter lumen with heparinized saline.

**Caution:** If flushing is not done, the blood could coagulate within the catheter lumen, leading to occlusion of the lumen.




10. After determining the position of the placement of the balloon catheter, fix the wing and Y-connector by suturing to the skin or attach using Statlock® devices.




## Preparation for pumping

**Caution:** The Insightra IAB Catheter is provided with custom adapters for use with Arrow and Datascope IAB pumps.
- Performance testing has been completed using Datascope and Arrow pumping systems.
- The recommended maximum heart rate should not exceed 140 bpm. Higher heart rates on some IAB pumps may result in decreased augmentation.
- Refer to the table below for the only compatible pumps that have been validated for use with the Insightra IAB catheter.

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

**Caution:** The model IMU7F-20 with 20cc balloon volume is not compatible with Arrow IAB pumps.

**Connection of IAB catheter to pump using the extension tubing set**
1. Select the appropriate IAB pump adaptor extension tubing set for either Arrow or Datascope IAB pumps.
2. Remove the one way valve from the main unit tube.
- When using an Arrow IAB pump, connect the IAB catheter’s female luer connector to the male luer connector of the Arrow extension tubing set. Connect the male adaptor at the other end of the extension tubing set to the appropriate IAB pump.
- When using a Datascope IAB pump, connect the IAB catheter’s female luer connector to the male luer connector of the Datascope extension tubing set. Connect the male adaptor at the other end of the extension tubing set to the safety disk/chamber of the appropriate IAB pump.

3. Follow appropriate IAB pump instruction manual for balloon purge procedures.

**Caution:** Confirm that all connections are securely attached and leak free. Only one extension tubing set should be used to connect the IAB catheter to an IAB pump. The extension tubing sets are sterile and should only be used once.

**Setting of the balloon volume**
1. Adjust the balloon volume in accordance with the IFU or the instruction manual of the IAB pump.
- For Datascope pumps, setting of the balloon volume is not required.
- For Arrow pumps, the balloon volume is automatically set when the connector is attached to the IAB pump. However, for balloon Sizes M and S, lower the inflation volume by 5cc in accordance with the IFU or instruction manual of the IAB pump.

## Start of IAB pumping treatment

1. Follow the respective IAB pump manufacturers instructions for details regarding balloon purge, start-up procedures and general operation.
2. Start pump in accordance with the instruction manual of the IAB pump.
3. If after a few cycles of counterpulsation, it appears that the balloon membrane is not fully open, perform the following procedure:

   a) Determine the required preload volume of air or helium. The pre-load volume = pumping volume + 10cc for balloon sizes L, M, and MS. The pre-load volume = pumping volume + 5cc for balloon sizes S, and SS.
   b) Fill the 60cc syringe with determined pre-load volume of air or helium.
   c) Disconnect the extension tube and connect the 60cc syringe to the female luer of the main unit tube, and conduct “pre-load” manually.

**Warning:** Never inject air/helium into the central lumen.
**Caution:** Do not perform manual pre-load with the extension tubing set attached to the catheter.
   d) Immediately aspirate the air/helium from the catheter.

**Caution:** If pre-load is not implemented, the balloon membrane may not unfold and the balloon will not dilate during inflation.
4. When starting the IABP treatment, initially actuate at 1:2, and confirm that the balloon is dilating correctly.
5. Manage the central lumen and pressure lines in accordance with standard hospital procedures.

**Caution:** Once normal pumping is initiated, if dilation inflation of the balloon is not within the desired range, alter the gas volume within the balloon and the pump timing in accordance with the instruction manual of the IAB pump.
**Caution:** If abnormal bleeding or hematoma in the subcutaneous tissue is observed, treat according to normal hospital practices.
**Caution:** Regularly check the peripheral circulation in order to prevent ischemic damage in the lower extremities. If optimal IAB catheter operation is not obtained after the start of balloon pumping, the following factors should be considered.

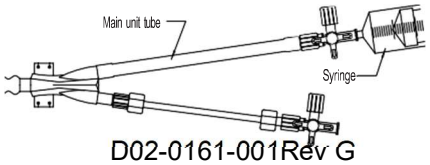
| Factors | Improvement measures |
|---|---|
| The balloon is placed in an improper position such as in a toruous blood vessel. | Re-position the balloon and obtain fluoroscopic confirmation. |
| Complete dilation is not obtained because the balloon volume is too large vs. the patient’s aorta. | Change the balloon to the appropriate size. |
| A portion of the balloon is not completely out of the tip of the sheath. | Re-position the balloon until it is completely out of the sheath. |
| The balloon set volume of the pump is too low. | Change the balloon set volume, referring to the instruction manual of the pump. |
| The wrapping of the balloon is too tight to be loosened. | Manually dilate/inflate the balloon using the syringe. |
| Constriction of the gas lumen due to kink/collapse of the catheter shaft. | Straighten the constricted part. If not improved, remove it, and insert a new balloon catheter. |

Perform manual pre-load as described above.

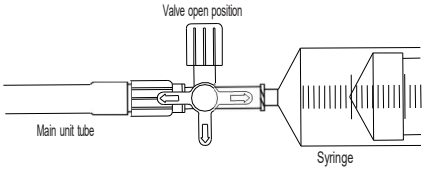
The physiological influence of the patient may affect the optimal performance of the IAB catheter as follows: mean arterial pressure is markedly low; or systemic vascular resistance is low; or the heart rate is fast, and the blood pumping in the cardiac ventricle is insufficient.

## Removal of balloon catheter

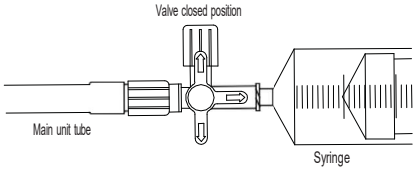
1. Stop the pumping of the balloon catheter in accordance with standard hospital practices.
2. Prior to removal, discontinue anticoagulation therapy or reduce its amount according to the judgment of the clinician.
3. Disconnect the main unit tube from the extension tube.
4. Connect a stop cock and syringe to the main unit tube.



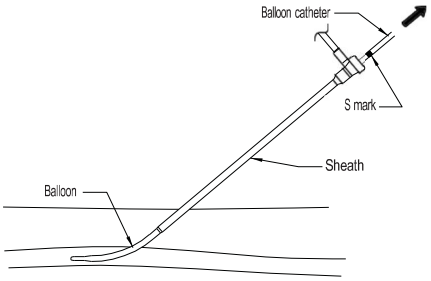
5. Confirm that the valve of the stop cock is open, and remove the gas from the balloon by drawing back on the syringe.




6. With the syringe in the drawn state, turn the handle of the stop cock toward the main unit tube, and close the valve.




7. Disconnect the Syringe from the four-way stop cock.
8. Close the four-way stop cock on the pressure monitoring extension and disconnect the pressure monitoring line.
9. In the case of insertion using a sheath, pull out the catheter from the body until the S-marker (the wide mark closest to the balloon) can be seen, supporting the sheath so that it does not move. When the S-marker is seen from the sheath, stop withdrawing the balloon catheter and remove the balloon and sheath in unison.




**Caution:** In the case of catheter insertion using a sheath, do not remove the catheter alone, leaving the sheath behind. The balloon may be damaged and a portion could be left in the blood vessel.

10. In the case of sheathless insertion, slowly pull out the balloon catheter from the patient.
11. In order to eliminate blood clot, back bleed for several seconds, and then compress the puncture site until achieving hemostasis.
12. After hemostasis is achieved, check the pulse at the foot and popliteal fossa, to ensure sufficient blood flow is maintained from the insertion site to the periphery.
13. After removal, inspect the entire balloon catheter (If a sheath was inserted, the sheath should also be inspected), and confirm that the entire device is completely removed and nothing was left behind.

**AFTER USE**

All components of the Intra Aortic Balloon Catheter Kit should be disposed of according to hospital guidelines for single use devices.

Note: After use this product should be considered a potential biohazard. Handle and recycle in accordance with accepted medical practice and applicable local, state and federal regulations.

| | Symbols |
|---|---|
| REF | Catalog Number |
| LOT | Lot Number |
| | Do not reuse<br>For single use only. |
| | Attention.<br>See Instructions for Use. |
| STERILE EO | Sterilized by ethylene oxide.<br>The product is Sterile if the pouch is not open or damaged. |
| QTY | Quantity |
| | Use by |
| | Manufacturer |
| Rx | Caution: Federal (USA) law restricts this device tosale by or on the order of a Physician |
| LATEX | Latex Free |

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INSIGHTRA® MEDICAL

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